Boehringer Ingelheim

March 25, 2021

**Boehringer Ingelheim**
**Animal Health USA Inc.**

www.boehringer-ingelheim.us

**Leann McAlister**
3239 Satellite Blvd.
Duluth, GA 30096

Attn: Robert Miller
VIA CDX PORTAL
Document Processing Desk – 6(a)(2)
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-3553

**SUBJECT**: Resubmission of all 2018 and 2019 FIFRA Section 6(a)(2) Aggregate Incident Reports for Frontline Spot-On Products

Per your request during our meeting on March 24, 2021, we are resubmitting all of the EPA Quarterly Aggregate Reports for 2018 and 2019 in support of EPA's preparation for a congressional inquiry into all spot-on pet products resulting from the recent Seresto collar articles.

Please note that all of these reports have been previously submitted via hard copy to include both Merial, Inc. and Boehringer Ingelheim Animal Health USA Inc.

If you have any questions regarding this report, please contact me at 678-638-3701 or via email at leann.mcalister@boehringer-ingelheim.com.

Sincerely,

Leann McAlister

Leann McAlister
Regulatory Affairs

Enclosure

MERIAL
3239 Satellite Boulevard
Duluth, Georgia 30096
Tel. : 1-678-638-3000

August 14, 2018

Document Processing Desk – 6(a)(2)
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-3553

**SUBJECT**: FIFRA Section 6(a)(2) Aggregate Incident Reports for 2Q18 (01Apr18 through 30Jun18)
Human and Domestic Animals in the US and Extraterritorial Associated with the Following Merial, Inc. Registrations:

- FRONTLINE® Spray Treatment, EPA Reg. No. 65331-1
- FIPAIRA® for Cats (formerly FRONTLINE® Top Spot for Cats), EPA Reg. No. 65331-2
- FIPAIRA® for Dogs (formerly FRONTLINE® Top Spot for Dogs), EPA Reg. No. 65331-3
- FRONTLINE® Plus for Cats, EPA Reg. No. 65331-4
- FRONTLINE® Plus for Dogs, EPA Reg. No. 65331-5
- CERTIFECT® for Dogs, EPA Reg. No. 65331-7

Please find enclosed the FIFRA 6(a)(2) Aggregate Incident Report for 2Q18, submitted in duplicate per the EPA's request on 30Nov12. Aggregate reports for humans (HD/HE: Minor/Unknown) and domestic animals are submitted quarterly. This report is also being provided as a .pdf file on CD-ROM per EPA's communication on 03Sept14. Since these products are produced and sold worldwide, Merial is providing worldwide reporting of adverse events for the aforementioned products.

If you have any questions regarding these reports, please contact me at (678) 638-3948 or via email at timothy.dotson@merial.com.

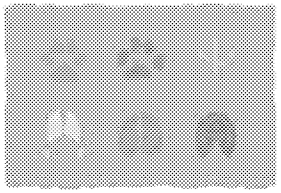
Sincerely,

Timothy A. Dotson
Regulatory Affairs North America

Enclosure

www.merial.com

# EPA Quarterly Aggregate Report



Number of Incidents and Adverse Effects Reported by Exposure Type and Severity Category (USA)
Reporting Period: 01-Apr-2018 to 01-Jul-2018 [1]
Product Family: Frontline Products (include non-specific)

| Generic Name / USA Registration Number | Total Incidents | H-D Human - Minor Effects | H-E Human - Unknown, Unspecified or Delayed Effects | D-A Domestic Animal - Death | D-B Domestic Animal - Major Effects | D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified |
|---|---|---|---|---|---|---|
| FIPRONIL 10%/S METHOPRENE 12% SPOT ON / 65331-4 | 151 | 4 | 1 | 4 | 3 | 139 |
| FIPRONIL 10%/S METHOPRENE 9% SPOT ON / 65331-5 | 351 | 13 | 10 | 6 | 16 | 306 |
| FIPRONIL SPOT ON DOG / 65331-3 | 1 | 0 | 0 | 0 | 0 | 1 |
| FIPRONIL SPRAY / 65331-1 | 4 | 0 | 0 | 0 | 1 | 3 |
| **Totals** | **507** | **17** | **11** | **10** | **20** | **449** |



1. Due to system limitations the end date is displayed as 1 July 2018, however only cases with a date first valid from 1 April 2018 through 30 June 2018 are displayed.



USA off-Label species totals are included

Use in Off-Label Species (USA)
Reporting Period: 01-Apr-2018 to 01-Jul-2018 [1]
Product Family: Frontline Products (include non-specific)

| Generic Name / Registration Number<br>Species | Total Incidents | D-A Domestic Animal - Death | D-B Domestic Animal - Major Effects | D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified |
|---|---|---|---|---|
| FIPRONIL 10%/S METHOPRENE 12% SPOT ON / 65331-4 | 1 | 0 | 0 | 1 |
| Rabbit | 1 | 0 | 0 | 1 |
| FIPRONIL 10%/S METHOPRENE 9% SPOT ON / 65331-5 | 3 | 0 | 1 | 2 |
| Feline | 3 | 0 | 1 | 2 |
| **Totals** | **4** | **0** | **1** | **3** |



1. Due to system limitations the end date is displayed as 1 July 2018, however only cases with a date first valid from 1 April 2018 through 30 June 2018 are displayed.

Number of Incidents and Adverse Effects Reported by Exposure Type and Severity Category (Extraterritorial)
Reporting Period: 01-Apr-2018 to 01-Jul-2018 [1]
Product Family: Frontline Products (include non-specific)

| Generic Name / USA Registration Number | Total Incidents | H-D Human - Minor Effects | H-E Human - Unknown, Unspecified or Delayed Effects | D-A Domestic Animal - Death | D-B Domestic Animal - Major Effects | D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified |
|---|---|---|---|---|---|---|
| FIPRONIL 10%/S METHOPRENE 12% SPOT ON / 65331-4 | 186 | 2 | 0 | 2 | 3 | 179 |
| FIPRONIL 10%/S METHOPRENE 9% SPOT ON / 65331-5 | 365 | 0 | 0 | 4 | 3 | 358 |
| FIPRONIL SPOT ON CAT / 65331-2 | 129 | 1 | 0 | 3 | 0 | 125 |
| FIPRONIL SPOT ON DOG / 65331-3 | 209 | 1 | 0 | 3 | 0 | 205 |
| FIPRONIL SPRAY / 65331-1 | 288 | 2 | 0 | 6 | 3 | 277 |
| Frontline (Non-specific) / Frontline (Non-specific) | 1 | 0 | 0 | 0 | 0 | 1 |
| **Totals** | **1,178** | **6** | **0** | **18** | **9** | **1,145** |



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Extraterritorial off-Label species totals are included

Use in Off-Label Species (Extraterritorial)
Reporting Period: 01-Apr-2018 to 01-Jul-2018[1]
Product Family: Frontline Products (include non-specific)

| Country<br>Generic Name / USA Registration Number<br>Species | Total Incidents | D-A Domestic Animal - Death | D-B Domestic Animal - Major Effects | D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified |
|---|---|---|---|---|
| FIPRONIL 10%/S METHOPRENE 12% SPOT ON / 65331-4 | 1 | 0 | 0 | 1 |
| Rabbit | 1 | 0 | 0 | 1 |
| FIPRONIL SPOT ON CAT / 65331-2 | 3 | 1 | 0 | 2 |
| Canine | 1 | 0 | 0 | 1 |
| Rabbit | 2 | 1 | 0 | 1 |
| FIPRONIL SPOT ON DOG / 65331-3 | 3 | 0 | 0 | 3 |
| Feline | 3 | 0 | 0 | 3 |
| FIPRONIL SPRAY / 65331-1 | 1 | 1 | 0 | 0 |
| Rabbit | 1 | 1 | 0 | 0 |
| **Totals** | **8** | **2** | **0** | **6** |



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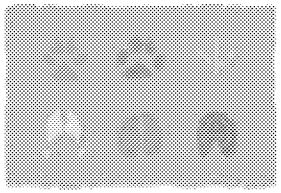
# EPA Report



## Worldwide Adverse Event Reports Involving - Animal Cases
## Reporting Period: 01-Apr-2018 to 01-Jul-2018 [1]

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 28-Jun-2018 | UAE; 17US086846; NY; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 01-Feb-2018* | 01-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 28 Jun 2018, the owner reported the following event for Jazz, 1 year old, 5 pound, spayed female, Domestic Shorthair feline.<br>1 May 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. The cat ran away and hid for 15 minutes. The pet experienced hypersalivation. The pets were not presented to the clinic and no treatment was provided. The pet recovered after 15 minutes.<br>The pet received the product since 1 Feb 2018 and not symptoms presented. There is 1 other cat in the household that also experienced symptoms (see case 18US042318). No further medical information is expected. |
| 24-Apr-2018 | UAE; 18AR000022; Don Torcuato, Provincia de Buenos Aires; Argentina | **Species:** Canine **Breed:** Pekingese **Sex:** M **Sex qualifier:** - **Age:** 17.00 Year(s) **Weight:** 7 - 8 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 17-Mar-2018 | 17-Mar-2018 | N/A | D-D | As reported by pet owner, Yony, 17 years, 7 to 8 kg proximally, canine, Pekinese, intact, received FRONTLINE PLUS 0-10 kg, batch unknown, expiry unknown, topically between the shoulder blades on 17/March/18. After product administration the animal continues having fleas.<br>She does not make environmental treatment |
| 26-Apr-2018 | UAE; 18AR000023; Buenos Aires; Argentina | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 3.600 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 04-Apr-2018 | 04-Apr-2018 | 0 Day(s) | D-D | As reported by pet owner, Teddy, a 8 years old canine, neutered, 3.600 kg, poodle toy, in good health status, received 0.67 ml of FRONTLINE SPOT ON DOG, batch unknown, expiry unknown,topically between the shoulder blades on 04 april 2018. The owner reported that the product had no effect and the dog still has fleas.<br>A BI technician talked to the owner and noticed that the quantity of fleas that can be observed on her dog are due to a large quantity of immature forms in the environment.<br>The owner does not make environmental treatment, so it was suggested the use of a methoprene product and recommended to vacuum the environment and monthly usage of Frontline. |

N/A signifies the information for this field is either not available or not applicable

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 10-May-2018 | UAE; 18AR000025; Lanus, Provincia de Buenos Aires; Argentina | **Species:** Canine **Breed:** Pekingese **Sex:** F **Sex qualifier:** - **Age:** 14.00 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 03-May-2018 | 03-May-2018 | 0 Day(s) | D-D | As reported by pet owner, Luna , 14 years approximately, 7 kg, canine, Pekinese<br>Intact, received RONTLINE PLUS 0-10 kg, batch 008/16, expiry October 2019, topically between the shoulder blades, 0,67 ml, administered by owner on 3 May 2018.<br>After product administration the animal continues having fleas .<br>The quantity of fleas that can be observed on her dog are due to a large quantity of in mature forms that are found in her house. She does not make environmental treatment.<br>It is the second pipette that was applied in the year. |
| 01-Jun-2018 | UAE; 18AR000029; Buenos Aires, Argentina; Argentina | **Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 28-May-2018 | 28-May-2018 | 0 Day(s) | D-D | As reported by the owner on 31th May 2018, a dog, 5 years, male sex, reproductive status good, and weight 6 kg, health status unknown, received 1 doses of FRONTLINE SPOT ON, batch unknown, expiry unknown, route unknown.<br>The dog received the pipette on 28 May 2018 and after that the dog presented clinical signs pruritus, and application site hair loss. The vet prescribed antibiotics and applied one doses of corticoid. The technical service will be calling the owner to collect more information.<br>Update 1-May The technical service could not communicate with the owner, she didn't´t answer the phone.<br>Update 7-June The Technical Services could talk the owner ( Paula Segula ). She said that the product involved was Frontline Spot on, and said that the product was administrated by Dr Leandro SALUM, so The Technical Services asked her to let me talk to the vet . She said that she would tell him to phone to me ; but she did not give me the phone number .<br>Dr Salum phone Technical Services told about the case . He put Frontline Spot on and 48 hours later the owner called Dr to tell that the dog had a red area in the place were the product was dropped. The Dr. told the owner to wash de area with cold water and then put Pervinox . As the lesion became to growth Dr Salum went to a visit and administrated corticoid and ATB. Today the dog is getting better. |
| 04-Jun-2018 | UAE; 18AR000030; Ciudadela, Buenos Aires; Argentina | **Species:** Canine **Breed:** Poodle (Standard) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 5 kg | 1 | - | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 18-May-2018 | 18-May-2018 | N/A | D-E | As reported by the owner on 4th June 2018, canine, unknown years, Poodle, female, reproductive status good, 5 kg, received 1 doses of FRONTLINE SPOT ON 0-10 KG, batch unknown, expiry unknown, topically between the shoulder blade<br>The dog received the pipette on 18 May 2018 and after product administration the animal continues having fleas.<br>Technical Services talked with the owner, the quantity of fleas that can be observed on her dog are due to a large quantity of immature forms that are found in her house. She does an environmental treatment with hexaclorid product ( Gamexane ) . Technical Services suggest that she should use a methoprene product and that it is important to vacuum the environment and advice on the importance of monthly usage of Frontline plus |
| 05-Jun-2018 | UAE; 18AR000032; Avellaneda, Buenos Aires; Argentina | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M | 1 | - | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other | 08-May-2018 | 08-May-2018 | N/A | D-E | As reported by reported by cat owner, Tom, 4th June 2018, 6 months years old, a, male, intact, 1 kg., Mixer breed, with good reproductive status, received FRONTLINE SPRAY x 250 ml, batch R01201A, expiry February/2020, topical on 08/May/18. After product administration the animal continues having fleas. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex qualifier:** -<br>**Age:** 6.00 Month(s)<br>**Weight:** 1 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | The Technical Service talked with the owner, the quantity of fleas that can be observed on her feline are due to a large quantity of immature forms that are found in her house.<br>The owner applies a product multi-dose bottle (Perfos of Kualcos laboratory) to the others cats and She does not make environmental treatment correctly.<br>The Technical Services suggest that she use a methoprene product and that it is important to vacuum the environment and advice on the importance of monthly usage FRONTLINE SPRAY. |
| 07-Jun-2018 | UAE; 18AR000034; -; Argentina | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 6.00 Month(s)<br>**Weight:** 1 kg | 1 | - | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 20-May-2018 | 20-May-2018 | N/A | D-E | As reported by reported by cat owner, Lucy, 6th June 2018, 6 months years old, a female, intact, 1 kg., Mixer breed, with good reproductive status, received FRONTLINE SPOT ON GATO, batch unknown, expiry unknown, topical on 20/05/18. After product administration the animal continues having fleas.<br>The Technical Service talked with the owner, the quantity of fleas that can be observed on her cat are due to a large quantity of immature forms that are found in her house. The owner pet does not make environmental treatment correctly.<br>The Technical Services suggest that she use a methoprene product and that it is important to vacuum the environment and advice on the importance of monthly usage FRONTLINE SPOT ON |
| 08-Jun-2018 | UAE; 18AR000036; Buenos Aires; Argentina | **Species:** Canine<br>**Breed:** Poodle (Standard)<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 6.00 Year(s)<br>**Weight:** 5 kg | 1 | - | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 15-May-2018 | 15-May-2018 | N/A | D-E | As reporter by the owner on 8th June 2018, a dog, unknown years, unknown sex, reproductive status unknown, and weight unknown, health status unknown, received 1 application of FRONTLINE SPRAY, batch unknown, expiry unknown, route unknown on 27-02-18. After product application the animal continues having fleas.<br>The technical service could not communicate with the owner, she didn't´t answer the phone.<br>Update 11th May 2018 As reported by pet owner, Bur, an approximately 6 years, male, intact, 9 kg., Poodle, with good reproductive status, received one vial Frontline Spray x 250 ml, batch RD1201A, expiry March 2017 ( product expired), topically between the shoulder blades on 15 May 2019. After product administration the animal continues having fleas.<br>The Technical Service talked with the owner and suggest that pet owner use a methoprene product and that it is important to vacuum the environment and advice on the importance of monthly usage Frontline Spray.<br>The pet owner has 10 Poodles that sleep wit her and she applied the expired product. |
| 19-Jun-2018 | UAE; 18AR000038; 1; Argentina | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** age unknown<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 19-May-2018* | time to onset unknown | D-E | As reported by pet owner a canine, age unknown, breed unknown, sex unknown reproductive and health status unknown, weight unknown,received Frontline Spot on dogs, batch 027/14, expiry Oct/18, topically, dose unknown on 19 May 2018 approx.<br>The owner talked to a Bi employee by phone and reported that the product had no effect and the dog still has fleas.<br>A BI technician tried to talk to the owner and called her several times with no answer. |
| 19-Jun-2018 | UAE; 18AR000039; | **Species:** Feline<br>**Breed:** Feline | 1 | 1 | 0 | **Product used:** FIPRONIL | 19-May-2018* | 19-May-2018* | 0 Day(s) | D-E | As reported by pet owner a feline, age unknown, breed unknown, sex unknown reproductive and health status unknown, weight |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1; Argentina | (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | unknown,received FRONTLINE PLUS CATS, batch 004/17, expiry Feb/20, topically, dose unknown on 19 May 2018 approx.<br>The owner talked to a Bi employee by phone and reported that the product had no effect and the cat still has fleas.<br>A BI technician tried to talk to the owner and called her several times with no answer. |
| 28-Jun-2018 | UAE; 18AR000042; La Plata, Buenos Aires, Argentina; Argentina | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** 50.00 Day(s)<br>**Weight:** 1 - 2 kg* | 2 | 2 | 2 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 25-Jun-2018 | 25-Jun-2018 | 0 Day(s) | D-A | As reported Dr. Arizaga, name unknown, 50 days, 1 to 2 kg approximately, canine, mixed breed, unknown reproductive status, received FRONTLINE SPRAY x 250 ml, batch unknown, expiry unknown, topical, dose: 15 mg per kg, administered by DVM on 25 June 2018. 20 minutes after product administration the owner took them to the veterinarian dead. The pappies were found the previous day on the street. |
| 19-Apr-2018 | UAE; 18AT000018; -; Austria | **Species:** Canine<br>**Breed:** German Shepherd Dog<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** 10.00 Month(s)<br>**Weight:** 27 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 2018* | 2018* | 0 Day(s) | D-E | As reported by the pharmacist, a 10-month old 27 kg German Shepard dog of unknown sex and reproductive status received FRONT-LINE SPOT ON DOG L (batch: M23110BR, expiry date: 31DEC2018, route: topical, dose: 1 pipette/2,68ml once in 4 weeks)<br>administered by the owner on an unknown date in 2018. In 2017, the dog was also treated, but the owner does not recall which product was used. After product administration (unknown time to onset) the animal experienced an enormous number of ticks which did not fall off. The dog had access to potentially infested environments (a field and garden).<br>The dog owner was familiar with the handling and use of Frontline; she had already used Frontline on other dogs in the past. |
| 19-Apr-2018 | UAE; 18AT000021; Austria; Austria | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 15-Apr-2018* | 19-Apr-2018* | 4 Day(s) | D-E | As reported by the pharmacist, a dog of unknown age, weight, breed and reproductive status received FRONTLINE SPOT ON DOG M on approximately 15APR2018 administered by the owner. Approximately 4 days after product administration (19APR2018) the animal experienced an increase in the number of ticks. The number of ticks had not decreased by 23APR2018. |
| 19-Apr-2018 | UAE; 18AT000022; Austria; Austria | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** - | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / | 15-Apr-2018* | 19-Apr-2018* | 4 Day(s) | D-E | As reported by the pharmacist, a cat of unknown age, weight, breed and reproductive status received FRONTLINE SPOT ON CAT on approximately 15APR2018 administered by the owner. Approximately 4 days after product administration (19APR2018) the animal experienced an increase in the number of ticks. The number of ticks had not decreased by 23APR2018. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Weight:** Unknown | | | | Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | |
| 08-May-2018 | UAE; 18AT000024; -; Austria | **Species:** Canine<br>**Breed:** German Shepherd Dog<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 30 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Route not indicated / recommended) | 17-Apr-2018* | 17-Apr-2018* | 0 Day(s) | D-D | As reported by the pharmacist, a 30 kg German Shepard dog of unknown age, sex and reproductive status received FRONTLINE SPOT ON DOG L (batch number: P21902CR, expiry date NOV2019) administered by the owner on 17APR2018 or 18APR2018 on the nape of the neck and rump directly on the skin. Starting on the day of product administration and at least up to the date of notifiying the pharmacy on 8MAY2018, the animal had 3 to 10 ticks on the face daily. The ticks had sucked on to the skin of the dog. The dog was not bathed during this time and had no contact with water. |
| 24-May-2018 | UAE; 18AT000028; -; Austria | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 40 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 01-May-2018* | N/A | D-E | As reported by the pharmacist, a dog of more than 40 kg of unknown age, breed and reproductive status received FRONTLINE COMBO SPOT ON DOGS XL administered by an unknown person on unknown dates (01MAY2018 was entered as default). The owner returned the package (2 pipets left inside as 1 pipet was used up from 3 pipets presentation) to the pharmacy because of noticing that the product is ineffective (start date of event unknown, 01MAY2018 entered as default). The attending veterinarian had also told the owner that Frontline has not worked for the past 3 years. |
| 29-May-2018 | UAE; 18AT000032; -; Austria | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018 | N/A | D-D | As reported by the pharmacist, an animal owner (we assume that the animal species is a cat)returned a package of FRONTLINE SPOT ON CAT, stating that it does not work.Star date is not known and 1st June has been entered by default. |
| 03-Apr-2018 | UAE; 18AU000387; -; Australia | **Species:** Canine<br>**Breed:** Spaniel (Brittany)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 12 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 30-Jun-2010* | 01-Apr-2018* | 1 Day(s) | D-D | As reported by the owner, Leon, a male, neutered, 8 year old, Brittany Spaniel, weighing approximately 12 kg, received one dosage form of FRONTLINE PLUS DOG M (FIPRONIL 10%/S METHOPRENE 9% SPOT ON, Batch M61512AL, Expiry 03/2018), administered topically by the owner for flea and tick control on 31 March 2018. The product has been administered regularly since 2010. The owner has noted the dog has been very itchy for the past week and is causing self trauma to the skin. On inspection, the owner noted live fleas on him. No veterinary attention has been sought at the time of reporting and the condition is ongoing. This is the extent of the information available. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 04-Apr-2018 | UAE; 18AU000423; -; Australia | **Species:** Canine **Breed:** Staffordshire Terrier **Sex:** F **Sex qualifier:** - **Age:** 4.50 Year(s) **Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2015* | 30-Jan-2018 | N/A | D-E | As reported by the owner, Bindi, approx 4.5 year old, 35kg, female, intact, American Staffy was given one pipette FRONTLINE PLUS DOG L 20-40kg (2.68 ml, 100g/L fipronil, 90g/L s-methoprene) for flea and tick protection. The owner has used the product for over 3 years. Since approx. the 30th of JAN 2018 the dog has had fleas, the owner has applied the product every 2 weeks for the past 10 weeks with no sign of controlling the fleas. The owner said he has washed the bedding and cleaned the environment and believes the product not to have worked. This is the extent of the information available at this time. |
| 12-Apr-2018 | UAE; 18AU000436; -; Australia | **Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.50 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 29-Mar-2018* | 11-Apr-2018* | 13 Day(s) | D-D | As reported by the owner, a 2.5 year old male desexed Jack Russell cross Poodle was administered FRONTLINE PLUS DOG M (P61506BL/R 06/19) for tick control on approximately 29 MAR 2018. The dog started showing signs of tick paralysis around 11 APR 2018. A dead tick was found in the dog's mouth, the dog was treated and recovered. This is the extent of the information available. |
| 25-Apr-2018 | UAE; 18AU000503; -; Australia | **Species:** Feline **Breed:** British Shorthair **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 5 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2003 | 01-Apr-2018* | 0 Day(s) | D-D | As reported by the owner, a 15 year old, approx. 5 kg, female, British Shorthair feline was given 1 dose of FRONTLINE PLUS FOR CATS 0.5mL (100g/L Fipronil 120g/L S-Methoprene) for flea protection on approx. 1st Apr 2018 for reporting purposes. Since the last application the cat has developed flea dermatitis and scabs. No vet attention has been sought and the condition of the cat is unknown. This is the extent of the information available. |
| 30-Apr-2018 | UAE; 18AU000521; QLD; Australia | **Species:** Canine **Breed:** Pug **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** No (Route not indicated / recommended) | 01-May-2018 | 01-May-2018 | 0 Day(s) | D-D | As reported by the attending veterinarian, 2 pugs of otherwise unknown signalment were given FRONTLINE PLUS DOG (product unsubstantiated) orally on food by accident by the owner on 1 MAY 2018. Later the same day the dogs both presented to the clinic with high temperatures, lethargy and heavy breathing. It is unknown if they have been treated and the condition was ongoing at the time of reporting. This is the extent of the information available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 01-May-2018 | UAE; 18AU000527; -; Australia | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 5 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 08-Dec-2017* | 10-Dec-2017* | 2 Day(s) | D-D | As reported by the owner, Charley, 14 year old, approx. 5kg, male neutered, Domestic Shorthair was given one dose of FRONTLINE PLUS FOR CATS 0.5mL (100g/L Fipronil, 120g/L S-Methoprene, Batch P41407AR/R and exp 10/2019) on approx. 8th Dec 2017 for flea control. Within 72 hours post application the owner noticed hair loss at the application site and a local dermatitis. No vet attention was sought and the cat has recovered (Approximately 1 JAN 2018). This is the extent of the information available. |
| 08-May-2018 | UAE; 18AU000547; -; Australia | **Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Neutered **Age:** 16.00 Month(s) **Weight:** 6 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2018* | 11-Apr-2018 | 0 Day(s) | D-D | As reported by the owner, Maggie, a female, neutered, 16 month old, Moodle, weighing approx. 6kg, received one dosage form of FRONTLINE ORIGINAL S (FIPRONIL SPOT ON DOG, Batch R20410AX, Expiry Jan 2020), administered topically by the owner for flea and tick control on approx 11 April 2018. Straight away the dog started to roll around on couches like she was trying to remove the product on and off for the next hour, the dog recovered a few hours later without veterinary treatment. The dog has had the product applied a few times before without incident. This is the extent of the information available. |
| 08-May-2018 | UAE; 18AU000554; -; Australia | **Species:** Feline **Breed:** Ragdoll **Sex:** M **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 10 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 27-Mar-2018 | 27-Mar-2018 | N/A | D-D | As reported by the owner, Smudge, a male, neutered, 8 year old Ragdoll x Siamese, weighing approx 10 kg, received one dosage form of FRONTLINE PLUS FOR CATS (FIPRONIL 10%/S METHOPRENE 12% SPOT ON, Batch P41407AR/R, Expiry 10/2019), administered topically by the owner for flea control on 24 April 2018. Note that it is possible that the cat is over 10 kg which would make this an underdose. Since the first application in 27 MAR 2018 the cat still has fleas, is overgrooming and has caused trauma to the tailbase area. This is the extent of the information available. |
| 24-May-2018 | UAE; 18AU000624; -; Australia | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 4.4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 05-Apr-2018* | 08-May-2018 | 3 Day(s) | D-D | As reported by the owner, Louisa, 4 year old, 4.4kg, female, desexed, feline of unknown breed received one dose of FRONTLINE ORIGINAL FOR CATS 0.5mL (100g/L Fipronil) on the 05th May 2018. On the 8th May 2018, the owner noticed localised hair loss and skin irritation. Vet attention was sought and the cat has been treated with cortisone injections, unknown anti-biotics and an unknown cream. The condition is still ongoing. This is the extent of the information available. |
| 04-Jun-2018 | UAE; 18AU000666; -; Australia | **Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Neutered | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON | 24-May-2018 | 29-May-2018* | 5 Day(s) | D-D | As reported by the pharmacist, Charlie, a female, neutered, 16 years old, Siamese cat, unknown weight, received one dosage form (0.5mL pipette) of FRONTLINE PLUS FOR CATS (100g/L fipronil / 120g/L (S)-methoprene, BA: R40506AW, EX: 04/2020), applied topically by the owner for flea control on the 24th May 2018. Approximately, within 4 days the owner noticed hair loss and |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Age:** 16.00 Year(s)<br>**Weight:** Unknown | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | redness at the site of application. The cat did not receive veterinary treatment and has recovered (approximately 31 MAY 2018). This is the extent of the information available. |
| 11-Jun-2018 | UAE; 18AU000687; -; Australia | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2016* | 02-Jan-2016* | 1 Day(s) | D-D | As reported by the owner, a dog of an unknown signalment, received an unknown dosage form of FRONTLINE PLUS DOGS (product batch, expiry and size are unsubstantiated), applied topically by the owner for flea and tick control on an unknown date (estimated for reporting purposes as 1 JAN 2016). In an unknown time frame the dog vomited (estimated as 2 JAN 2016). It is unknown whether the dog received veterinary treatment and the condition of the dog is unknown. This is the extent of the information available |
| 04-May-2018 | UAE; 18BE000060; -; Belgium | **Species:** Canine<br>**Breed:** Border Collie<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 24 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 04-May-2017* | 04-May-2017* | 0 Day(s) | D-D | As reported by the pharmacist (=pet owner), Indy, a 5 year and 9 month old, 24 kilograms, male castrated, Border Collie-Vizsla Mix dog received one vial of Frontline Spot-on L (Lot and Expiry date unknown, topically, between the shoulder blades) administered by the pet owner 1 year ago (exact date unknown), for flea and tick prevention. No other products were administered on the same date. The dog was in good health at the time of the administration. Immediately after product administration, the dog presented restless walking. A few hours later, the dog vomited gall during 3 days. The dog was not treated for this reaction and recovered on the 3th day. The pet owner also reported another dog from the same litter with similar reactions (See case 18BE000061). After this AE, the pet owner used Frontline Spot-on L two more times ( interval unknown) with similar reactions. It should be noted that the dog experienced a similar reaction after a previous treatment with Advantix. At the moment, the dog is treated with Stronghold for flea prevention without any side effects. No further information is expected. |
| 04-May-2018 | UAE; 18BE000061; -; Belgium | **Species:** Canine<br>**Breed:** Border Collie<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 24 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 04-May-2017* | 04-May-2017* | 0 Day(s) | D-D | As reported by the pharmacist (=pet owner), Dakotha, a 5 year and 9 month old, 24 kilograms, male castrated, Border Collie-Vizsla Mix dog received one vial of Frontline Spot-on L (Lot and Expiry date unknown, topically, between the shoulder blades) administered by the pet owner 1 year ago (exact date unknown), for flea and tick prevention. No other products were administered on the same date. The dog was in good health at the time of the administration. Immediately after product administration, the dog presented restless walking. A few hours later, the dog vomited gall during 3 days. The dog was not treated for this reaction and recovered on the 3th day. The pet owner also reported another dog from the same litter with similar reactions (See case 18BE000060). After this AE, the pet owner used Frontline Spot-on L two more times ( interval unknown) with similar reactions. It should be noted that the dog experienced a similar reaction after a previous |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | treatment with Advantix. At the moment, the dog is treated with Stronghold for flea prevention without any side effects . No further information is expected. |
| 16-May-2018 | UAE; 18BE000073; -; Belgium | **Species:** Canine **Breed:** German Shepherd Dog **Sex:** X **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 30 - 35 kg | 4 | 4 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 20-Apr-2018 | 20-Apr-2018 | 0 Day(s) | D-E | As reported by the owner, 4 White Shepherd dogs from the same household (mother, father, son, daughter), 2-5 years old, 30-35kg, received each one pipette Frontline Comboline L (lot and expiry date unknown, topically between the shoulder blades, massaged with the pipette) applied by the reporter on 20 april 2018 for tick prevention. The owner complained about the lack of efficacy of Frontline Comboline L because one week after product administration he noticed living ticks on his dogs after a walk. 3 years ago, the owner switched from Frontline Spot-on to Frontline Comboline on the recommendation of his pharmacist, because he also noticed living ticks unless treatment. In the last 3 years, he didn't have complaints about the efficacy against ticks except for this year. The dogs are treated every month with Frontline Comboline and are not frequently exposed to water. |
| 28-May-2018 | UAE; 18BE000078; -; Belgium | **Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** - **Age:** 11.00 Week(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** - | 26-Mar-2018* | 26-Mar-2018* | N/A | D-D | As reported by the attending vet, Lola, a female Old German Shepherd Dog of 11 weeks (approximately), received FRONTLINE SPOT ON (batch, expiry date unknown) administered topically in the neck by the owner on 26MARCH2018 (approximately). Shortly after product administration, the dog showed abnormal behaviour: circling, vocalisation, restlessness, biting towards the tail and thighs. These symptoms gradually disappeared during the following 8 weeks after product administration. On 21 MAY2018 (approximately), the dog received a second treatment with FRONTLINE SPOT ON (batch, expiry date unknown) administered topically in the neck by the owner. The same symptoms reappeared at the same day of product administration. UPDATE 29MAY2018: The involved product was FRONTLINE COMBO LINE M, batch P63210BL, expiry date 11/2019. |
| 06-Jun-2018 | UAE; 18BE000085; -; Belgium | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** Unknown **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 31-May-2018* | 05-Jun-2018 | 5 Day(s) | D-E | As reported by the pharmacist, a dog (age, weight, breed, reproductive status unknown) was treated with Frontline Combo Large (batch & expiry date unknown) administered by the dog owner around 31MAY18. On 05JUN18 the dog owner complained to the pharmacist that the product was not effective, since she saw a lot of ticks on the dog and falling of the dog.The product was collected at the pharmacy for further analysis. |
| 11-Jun-2018 | UAE; 18BE000086; -; Belgium | **Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** U **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous | 21-May-2018 | 21-May-2018 | 0 Day(s) | D-E | As reported by the owner, a 4 year old Pinscher (weigh, sex and reproductive status unknown) was treated with Frontline Combo Line S (expiry date 01/2019, batch number unknown) on 31 MAY18 administered by the dog owner. It was unclear from the dog owner's statement if the dog was already infested with fleas at the moment of administration. The owner still noted fleas after the administration and shampood the dog two weeks later with an unknown product that acts against fleas. Because the flea problem persisted, the owner adminstered a second dose of Frontline Combo on 10JUN2016. |

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| | | | | | | **Was the product used ok?:** Unknown to Company | | | | | |
| 26-Jun-2018 | UAE; 18BE000092; -; Belgium | **Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Neutered **Age:** 17.00 Year(s) **Weight:** 2.5 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 15-Apr-2018* | 15-Apr-2018* | N/A | D-E | Suspected lack of efficacy claim: As reported by the owner, a 17 years old, 2.5 kilograms, male, European Shorthair cat, received 3 pipettes of Frontline Combo Cat (lot and expiry date unknown, topically, in the neck) applied by the owner since 2 months ago (15 June 2018 – estimated start date) with a 3 weeks interval, for flea control. The owner complained about the lack of efficacy of Frontline because after 2 months she still found some fleas on her cat and she and her children got fleabites. Last month, the cat was not allowed to access to the house. The house was treated with an environment spray (product unknown). |
| 02-Apr-2018 | UAE; 18BR002707; -; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 02-Apr-2018* | 4 Week(s) 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Mar 2018 - chosen at random). The owner believes that FL is not working. No ectoparasites were reported. This is the extent of the information available. |
| 02-Apr-2018 | UAE; 18BR002720; SP; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 02-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Billy, a male Lhasa Apso of 9 months old and 8 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (004/17 and unknown exp date, topical, btw the shoulder blades), applied by the reporter one week ago (26 Mar 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, Billy is scratching himself due to fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 02-Apr-2018 | UAE; 18BR002722; SP; Brazil | **Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Pregnant **Age:** 14.00 Month(s) **Weight:** 25 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Mar-2018* | 02-Apr-2018* | 13 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Laica, 14 months old, 25 kg, female, Pit Bull , received 1 pipette of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp unknown, topically, between the shoulder blades), applied by the owner, on 20 Mar 2018, for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her pet. According to the owner, animal already had fleas 1 month prior to treatment. The environment has been treated with BUTOX®. No further information is available. |
| 02-Apr-2018 | UAE; | **Species:** Canine | 1 | 1 | 0 | **Product used:** | N/A | 02-Apr-2018* | 13 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 18BR002724; PR; Brazil | **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 5 kg | | | | FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | Fred, a male Shih Tzu of 6 years old and 5 kg, received one vial of FRONTLINE PLUS DOG S (FL) (018/17, May 2019, topical, btw the shoulder blades), applied by the reporter on 20 Mar 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases were reported on 18BR002725, 18BR002726, 18BR002727 and 18BR002728. No further information is expected. |
| 02-Apr-2018 | UAE; 18BR002725; PR; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 02-Apr-2018* | 13 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Chica, a female Shih Tzu of 3 years old and 3 kg, received one vial of FRONTLINE PLUS DOG S (FL) (018/17, May 2019, topical, btw the shoulder blades), applied by the reporter on 20 Mar 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases were reported on 18BR002724, 18BR002726, 18BR002727 and 18BR002728. No further information is expected. |
| 02-Apr-2018 | UAE; 18BR002754; PR; Brazil | **Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 30 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 24-Mar-2018 | 02-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy claim : As reported by the owner, Isis, 4 years old, 30 kilogram, canine, female, Labrador, received 1 pipette of FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 24 Mar 2018, for flea treatment. The owner complained about the lack of efficacy of FL because she continued to find fleas in her pet. According to the owner, her pet already had fleas 1 week prior to treatment. The environment has been treated but the owner couldn´t inform the products name. There are another 2 dogs in the same household with similar problem (see cases 18BR002755 and 18BR002756). The owner said that she had used FRONTLINE SPOT-ON DOGS® in the past without issues. No further information is available. |
| 02-Apr-2018 | UAE; 18BR002755; PR; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 24-Mar-2018 | 02-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy claim : As reported by the owner, Thor, 10 years old, 15 kilogram, canine, male, Mixed Breed, received 1 pipette of FRONTLINE PLUS DOG M (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 24 Mar 2018, for flea treatment. The owner complained about the lack of efficacy of FL because she continued to find fleas in her pet. According to the owner, her pet already had fleas 1 week prior to treatment. The environment has been treated but the owner couldn´t inform the products name. There are another 2 dogs in the same household with similar problem (see cases 18BR002754 and 18BR002756). The owner said that she had used FRONTLINE SPOT-ON DOGS® in the past without issues. No further information is available. |
| 02-Apr-2018 | UAE; 18BR002756; PR; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products | 24-Mar-2018 | 02-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy claim : As reported by the owner, Zaira, 3 years old, 15 kilogram, canine, female, Mixed Breed, received 1 pipette of FRONTLINE PLUS DOG M (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 24 Mar 2018, for flea treatment. The owner complained about the lack of efficacy of FL because she continued to find fleas in her pet. According to the owner, her pet already had fleas 1 week prior to treatment. The environment has been treated but the |

N/A signifies the information for this field is either not available or not applicable

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Weight:** 15 kg | | | | **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | owner couldn´t inform the products name. There are another 2 dogs in the same household with similar problem (see cases 18BR002754 and 18BR002755). The owner said that she had used FRONTLINE SPOT-ON DOGS® in the past without issues. No further information is available. |
| 03-Apr-2018 | UAE; 18BR002759; SP; Brazil | **Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 34 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 21-Mar-2018 | 23-Mar-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy claim : As reported by the owner, Manu, 8 years old, 34 kilogram, canine, female, Golden Retriever, received 1 pipette of FRONTLINE SPOT-ON DOGS L (FL) (lot 012/16 and exp date unknown, topically, between the shoulder blades), applied by the owner on 21 Mar 2018, for flea treatment. The owner complained about the lack of efficacy of FL because she continued to find fleas in her pet. According to the owner, her pet already had fleas 1 week prior to treatment. The environment has been treated with BUTOX®. The owner also believes the animal might have had an adverse reaction to the product (see case 18BR002760). No further information is available. UPDATE 4 MAR 2018 - According to the owner, it was the first time that FL had been applied. No further information is known. |
| 03-Apr-2018 | UAE; 18BR002760; SP; Brazil | **Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 34 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 21-Mar-2018 | 21-Mar-2018* | 0 Day(s) | D-D | Suspected Adverse Event : As reported by the owner, Manu, 8 years old, 34 kilogram, canine, female, Golden Retriever, received 1 pipette of FRONTLINE SPOT-ON DOGS L (FL) (lot 012/16 and exp date unknown, topically, between the shoulder blades ), applied by the owner on 21 Mar 2018, for flea treatment. The owner complained that her animal is scratching and have skin lesion. According to the owner it is the first time Manu got fleas and she is uncertain if the reactions might be due to flea allergy dermatitis. The owner also complained about the lack of efficacy of FL (see case 18BR002759). It is unknown if the animal was taken to the veterinary. No further information is available. UPDATE 4 MAR 2018 - According to the owner, it was the first time that FL had been applied. Following product application (unknown date), the pet also presented with red spots around the body. No vet care was provided and the symptoms are still ongoing. No further information is available. |
| 02-Apr-2018 | UAE; 18BR002763; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 30-Mar-2018 | 2 Day(s) | D-D | Suspected Lack of Efficacy claim : As reported by the owner, Lili, 6 years old, 5 kilogram, canine, female, Mixed Breed, received 1 pipette of FRONTLINE PLUS CAT (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner on 28 Mar 2018, for flea treatment. The owner complained about the lack of efficacy of FL because she continued to find fleas in her pet. According to the owner, her pet already had fleas 2 months prior to treatment. The environment has been treated with BUTOX®. There is also a dog in the same household but he is treated and do not present fleas. The neighbor´s cat sometimes stays in her house roof. No further information is available. |
| 03-Apr-2018 | UAE; 18BR002764; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products | N/A | 03-Apr-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sofi, a female mixed breed cat of 5 years old and 5 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 30 Mar 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. Similar cases were reported on |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 5 kg | | | | **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | 18BR002765 and 18BR002766. No further information is expected. |
| 03-Apr-2018 | UAE; 18BR002765; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 03-Apr-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Joly, a female mixed breed cat of 5 years old and 5 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 30 Mar 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. Similar cases were reported on 18BR002764 and 18BR002766. No further information is expected. |
| 03-Apr-2018 | UAE; 18BR002766; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 03-Apr-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Snobel, a male mixed breed cat of 4 years old and 5 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 30 Mar 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. Similar cases were reported on 18BR002764 and 18BR002765. No further information is expected. |
| 03-Apr-2018 | UAE; 18BR002770; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 02-Apr-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the retail store staff member (who is also the pet owner), Panfi, a 3-month-old, 1 kg, male mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, near 28 Mar 2018, for flea treatment. Lack of efficacy suspected because the owner discovered fleas on her cat yesterday (2 Apr 2018). Flea infestation 10 days prior to FL, environment treated with Decaplus. It is unknown if FRONTLINE was applied to the cat in the past. No further information is available. |
| 03-Apr-2018 | UAE; 18BR002774; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 12 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the** | N/A | 03-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female medium crossbred dog of 2 years old and 12 kg, received one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, back - incorrect application), applied by the reporter on 27 Mar 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. No further information is expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **product used ok?:** No (Treatment / vaccination program not respected) | | | | | |
| 03-Apr-2018 | UAE; 18BR002775; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 03-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bido, a male Poodle of 4 years old and around 6 kg, was treated with FRONTLINE SPRAY (FL) (003/17 and unknown exp date, topical, whole body), applied by the reporter on 3 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and FL was applied in the past with no issue (1 Jan 2017 - chosen at random). No further information is expected. |
| 03-Apr-2018 | UAE; 18BR002778; PE; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 500 gms | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 03-Apr-2018* | 8 Week(s) 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Joaquina, a female mixed breed cat of 3 months old and 500 g, was treated with FRONTLINE SPRAY (FL) (004/16, Apr 2019, topical, whole body), applied by the reporter on 1 Feb 2018 (estimated date), for flea treatment. Lack of efficacy is suspected because fleas were found on her pet. The environment has been treated with cypermethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 03-Apr-2018 | UAE; 18BR002779; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 2.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 03-Apr-2018* | 20 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Tunico, a male Yorkshire of 3 years old and 2.1 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, back - incorrect application), applied by the reporter on 14 Mar 2018, for tick control. Lack of efficacy is suspected because the pet has ticks. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 02-Apr-2018 | UAE; 18BR002781; ES; Brazil | **Species:** Canine **Breed:** Bull Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 3.50 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 20-Mar-2018* | 01-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Branca, a 3.5-year-old, female Bull Terrier (weight unknown), was treated with one vial of FRONTLINE SPOT-ON DOGS (size, lot and exp unknown), by unknown, for the first time, on date not specified (20 Mar 2018 chosen at random), for flea and tick prevention. Lack of efficacy suspected because the owner discovered fleas and ticks on his dog on date not specified. Current status unknown. Branca was usually treated with other company's products with no issues. This is the extent of the information available for now. |
| 03-Apr-2018 | UAE; 18BR002788; | **Species:** Canine **Breed:** Canine | 1 | 1 | 0 | **Product used:** FIPRONIL | 01-Mar-2017* | 15-Mar-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one dog of unknown signalment was treated with |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | PE; Brazil | (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | FRONTLINE (unsubstantiated) (lot and exp unknown), by the reporter, on date not specified (15 Mar 2018 chosen at random). Lack of efficacy suspected because the dog continued to have ectoparasites. The product has been applied for the past 12 months approximately (dose frequency unknown and first application on date not specified – 1 Mar 2017 chosen at random), and that was not the first time that FRONTLINE did not work. This is the extent of the information available. |
| 04-Apr-2018 | UAE; 18BR002790; RJ; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 13.00 Year(s)<br>**Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 04-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Frederico, 13 years old, 14 kilogram, canine, male, Mixed Breed received a pipette of FRONTLINE SPOT-ON DOGS M (FL)(lot, exp date, topically, between the shoulder blades ) applied by the owner 7 days ago (28 Mar 2018 – estimated date), for lice treatment The owner complained about the lack of efficacy, because her Frederico remained with lice and he also got ticks. The environment has been treated with BUTOX®. The dog does walks on the street. The owner noticed parasites on her house´s wall. There is no further information available. |
| 04-Apr-2018 | UAE; 18BR002791; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 27-Mar-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Maria Isabel, a 3.5 kg, female mixed breeds cat (age unknown), was treated with unknown dose of FRONTLINE SPOT-ON DOG M (FL) (006/17, exp unknown), 1 vial for 3 cats, topic, base of skull and btw the shoulder blades, by the reporter, 15 days ago (20 Mar 2018), for flea control. Lack of efficacy suspected because the owner discovered fleas on her cat 1 week post product application, and she is still infested. Environment not treated. 2 other cats also treated with FL were reported on 18BR002792 and 18BR002793. No further information is available. |
| 04-Apr-2018 | UAE; 18BR002792; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Month(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 27-Mar-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Amorinha, a 6-month-old, 2 kg, female mixed breeds cat, was treated with unknown dose of FRONTLINE SPOT-ON DOG M (FL) (006/17, exp unknown), 1 vial for 3 cats, topic, base of skull and btw the shoulder blades, by the reporter, 15 days ago (20 Mar 2018), for flea control. Lack of efficacy suspected because the owner discovered fleas on her cat 1 week post product application, and she is still infested. Environment not treated. 2 other cats also treated with FL were reported on 18BR002791 and 18BR002793. No further information is available. |
| 04-Apr-2018 | UAE; 18BR002793; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG | N/A | 27-Mar-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mathias, a 4.8 kg, male mixed breeds cat (age unknown), was treated with unknown dose of FRONTLINE SPOT-ON DOG M (FL) |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 4.8 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | (006/17, exp unknown), 1 vial for 3 cats, topic, base of skull and btw the shoulder blades, by the reporter, 15 days ago (20 Mar 2018), for flea control. Lack of efficacy suspected because the owner discovered fleas on her cat 1 week post product application, and she is still infested. Environment not treated. 2 other cats also treated with FL were reported on 18BR002791 and 18BR002792. No further information is available. |
| 04-Apr-2018 | UAE; 18BR002799; BA; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 18 kg | 3 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 04-Apr-2018 | 25 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Jo, 7 years old, 18 kilogram, canine, female, Mixed Breed received a pipette of FRONTLINE SPOT-ON DOGS M (FL)(lot, exp date, topically, between the shoulder blades) applied by the owner on 10 Mar 2018, for flea treatment The owner complained about the lack of efficacy, because her animal the flea problem was solved but the animal got ticks. The environment has been treated with AMITRAZ®. The dog does walks on the street and has contact with other dogs. There are also 2 other dogs in the same household who have been treated and does not present any issue. There is no further information available. |
| 04-Apr-2018 | UAE; 18BR002805; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 04-Apr-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Condi, a male mixed breed cat of approximately 6 years old and around 7 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter one month ago (4 Mar 2018 – estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The surrounding environment has not been treated. FL was applied in the past with no issue (1 Jan 2017 - chosen at random). Similar cases were reported on 18BR002806 to 18BR002811. No further information is expected. |
| 04-Apr-2018 | UAE; 18BR002806; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 10.00 Year(s)<br>**Weight:** 5 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 04-Apr-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pepita, a female mixed breed cat of 10 years old and around 5 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter one month ago (4 Mar 2018 – estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The surrounding environment has not been treated. FL was applied in the past with no issue (1 Jan 2017 - chosen at random). Similar cases were reported on 18BR002805, 18BR002807 to 18BR002811. No further information is expected. |
| 04-Apr-2018 | UAE; 18BR002807; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products** | 01-Jan-2017* | 04-Apr-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Alice, a female mixed breed cat of 5 years old and 5 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter one month ago (4 Mar 2018 – estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. |

N/A signifies the information for this field is either not available or not applicable

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 5 kg* | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | The surrounding environment has not been treated. FL was applied in the past with no issue (1 Jan 2017 - chosen at random). Similar cases were reported on 18BR002805, 18BR002806, 18BR002808 to 18BR002811. No further information is expected. |
| 04-Apr-2018 | UAE; 18BR002808; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 5 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 04-Apr-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Ana, a female mixed breed cat of approximately 6 years old and around 5 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter one month ago (4 Mar 2018 – estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The surrounding environment has not been treated. FL was applied in the past with no issue (1 Jan 2017 - chosen at random). Similar cases were reported on 18BR002805, 18BR002806, 18BR002807, 18BR002809 to 18BR002811. No further information is expected. |
| 04-Apr-2018 | UAE; 18BR002809; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 5 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 04-Apr-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Fufu, a male mixed breed cat of approximately 6 years old and around 5 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter one month ago (4 Mar 2018 – estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The surrounding environment has not been treated. FL was applied in the past with no issue (1 Jan 2017 - chosen at random). Similar cases were reported on 18BR002805 to 18BR002808, 18BR002810 and 18BR002811. No further information is expected. |
| 04-Apr-2018 | UAE; 18BR002810; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 5 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 04-Apr-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sidy, a male mixed breed cat of approximately 6 years old and around 5 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter one month ago (4 Mar 2018 – estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The surrounding environment has not been treated. FL was applied in the past with no issue (1 Jan 2017 - chosen at random). Similar cases were reported on 18BR002805 to 18BR002809 and 18BR002811. No further information is expected. |
| 04-Apr-2018 | UAE; 18BR002811; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Year(s)<br>**Weight:** 5 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | 01-Jan-2017* | 04-Apr-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nino, a male mixed breed cat of 9 years old and around 5 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter one month ago (4 Mar 2018 – estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The surrounding environment has not been treated. FL was applied in the past with no issue (1 Jan 2017 - chosen at random). Similar cases were reported on 18BR002805 to |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | 18BR002810. No further information is expected. |
| 04-Apr-2018 | UAE; 18BR002812; SP; Brazil | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 04-Apr-2018* | 25 Day(s) | D-D | Suspected Lack of Efficacy claim : As reported by the owner, Lebel, 4 years old, 8 kilogram, canine, female, Poodle, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 10 Mar 2018, for flea treatment. The owner complained about the lack of efficacy of FL because she continued to find fleas in her pet. According to the owner, her pet already had fleas 2 to 3 months prior to treatment. The environment has been treated with SANOL®. The owner already used FRONTLINE SPOT-ON DOGS® in the past with no issues. No further information is available. |
| 04-Apr-2018 | UAE; 18BR002813; SP; Brazil | **Species:** Canine<br>**Breed:** Pug<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Month(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 15-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sheik, a 4-month-old, 6 kg, male Pug, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (006/16, exp unknown), topic, between the shoulder blades, by the reporter, on 14 Mar 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 2 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the cat in the past. One cat of the same household that is also on FRONTLINE was reported on 18BR002814. No further information is available. |
| 04-Apr-2018 | UAE; 18BR002814; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 15-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Verão, a 3-year-old, 4 kg, female mixed breeds cat, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (021/16, exp unknown), topic, between the shoulder blades, by the reporter, on 14 Mar 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 2 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the cat in the past. One dog of the same household that is also on FRONTLINE was reported on 18BR002813. No further information is available. |
| 04-Apr-2018 | UAE; 18BR002820; PR; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 6.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 04-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dora, a female Lhasa Apso of 2 years old and 6.6 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 26 Mar 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites. Dora has flea/tick allergic dermatitis and she is scratching herself due to ectoparasites. The environment has not been treated. FL was also applied on 1 Feb 2018 and it has been applied around 3 times a year (first application - 1 Jan 2017 - chosen at random). No further information is expected. |
| 02-Apr-2018 | UAE; 18BR002823; | **Species:** Canine<br>**Breed:** Shih Tzu | 1 | 1 | 0 | **Product used:** FIPRONIL | N/A | 02-Apr-2018* | 18 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female Shih Tzu of unknown signalment received |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | MG; Brazil | **Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 7 kg | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | 'FRONTLINE DOG S' (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 15 Mar 2018 (chosen at random). Lack of efficacy is suspected because the pet is infested by ticks. This is the extent of the information available. UPDATE 5 APR 2018 – Jolie, 1 year old, 7 kilogram, canine, female, Shih Tzu, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), administered by the owner on 22 Mar 2018, for tick control. The environment has not been treated. No further information is available. |
| 03-Apr-2018 | UAE; 18BR002826; SP; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 11-Mar-2018* | 12-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment was treated with one vial of FRONTLINE PLUS DOGS (size, lot and exp unknown), by the reporter, more than 20 days ago (11 Mar 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. This is the extent of the information available. UPDATE 5 APR 2018 – The pet owner was contacted and she reported that Luck, a 3-year-old, 6 kg, male Lhasa Apso, was treated with FRONTLINE PLUS DOG S (FL), topic, base of skull and btw the shoulder blades, for the first time, 25 days ago approximately. Flea infestation 2 months prior to FL, environment treated, daily outdoor access. FRONTLINE SPOT-ON DOGS was applied in the past with no issues. There is no further information expected. |
| 03-Apr-2018 | UAE; 18BR002827; MG; Brazil | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 16-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female dog, less than 4 kg (other signalment unknown), was treated with one vial of FRONTLINE (size, lot and exp unknown), by the reporter, on date not specified (15 Mar 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. This is the extent of the information available. |
| 04-Apr-2018 | UAE; 18BR002829; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Month(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 22-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bonnie, an 8-month-old, 2 kg, female mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, 'according to the product instructions ' (topic, between the shoulder blades), by the reporter, 2 weeks ago (21 Mar 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation prior to FL, environment not treated. One other cat of the same household that is also on FL was reported on 18BR002830. There is a dog in the same household that was treated with other company's product and is not infested by fleas. No further information is available. |
| 04-Apr-2018 | UAE; 18BR002830; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products** | N/A | 22-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Clyde, an 8-month-old, 2 kg, male mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, 'according to the product instructions ' (topic, between the shoulder blades), by the reporter, 2 weeks ago (21 Mar 2018), for flea treatment. Lack of efficacy suspected because |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Unknown<br>**Age:** 8.00 Month(s)<br>**Weight:** 2 kg | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | the cat continued to have fleas. Flea infestation prior to FL, environment not treated. One other cat of the same household that is also on FL was reported on 18BR002829. There is a dog in the same household that was treated with other company's product and is not infested by fleas. No further information is available. |
| 05-Apr-2018 | UAE; 18BR002833; SP; Brazil | **Species:** Canine<br>**Breed:** German Shepherd Dog<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Month(s)<br>**Weight:** 28 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 28-Mar-2018* | 01-Apr-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Angelis, a mlae German Shepherd Dog of 6 months old and 28 kg, received, for the first time, one vial of FRONTLINE PLUS DOG L (FL) (015/17 and unknown exp date, topical, btw the shoulder blades), applied by the reporter around 28 Mar 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has not been treated. There are two cats in this household that were not treated with any product against ectoparasites. No further information is expected. |
| 05-Apr-2018 | UAE; 18BR002837; -; Brazil | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Apr-2011* | 26-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, one cat, over 7 years old (other signalment unknown), was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), by the reporter, on date not specified (25 Mar 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. FRONTLINE was applied in the past 6-7 years with no issues (dose frequency unknown and 1st application on date not specified – 1 Apr 2011 chosen at random). There is no further information available. |
| 04-Apr-2018 | UAE; 18BR002841; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 31-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, an unknown number of cats received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not spcified (1 Apr 2018 - chosen at random). The owner believes that FL is not working because her animals are still scratching themselves. No ectoparasites were reported. FL was applied in the past with no issue (1 Jan 2017 - chosen at random). This is the extent of the information available. UPDATE 9 APR 2018 – The owner reported that Nick, a 4-year-old, 6 kg, male mixed breeds cat, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (005/17, exp unknown), topic, base of skull and btw the shoulder blades, on 30 Mar 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation one month prior to FL, environment not treated, outdoor access denied. There's a dog in the same household that was treated with other company's product and is not infested by fleas; and one other cat that is also on FL was reported on 18BR002885. There is no further information expected. |
| 04-Apr-2018 | UAE; 18BR002842; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG | 01-Apr-2016* | 03-Apr-2018 | 0 Day(s) | D-C | Suspected Adverse Event: As reported by the pet owner, Amora, a 3-year-old, 3 kg, female Yorkshire Terrier, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (020/16, exp unknown), |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 3 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | by the reporter, on 3 Apr 2018. Following product application, the dog experienced itching, 'irritation', cough, panting. UPDATE 5 APR 2018 – The pet owner was contacted and she reported that FL was applied topic, base of skull and btw the shoulder blades, for flea treatment. Amora was in good health prior to FL. Following product application (same day), she experienced appetite loss and apathy. Then, she also presented with cough, panting and agitation, all night long. She recovered by her own yesterday (4 Apr 2018). FRONTLINE has been applied in the past 2 years with no issues (dose frequency unknown and first application on date not specified (1 Apr 2016 chosen at random). No further information is available. |
| 04-Apr-2018 | UAE; 18BR002846; SP; Brazil | **Species:** Canine<br>**Breed:** Pug<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 7.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2017* | 02-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one female dog of unknown signalment was treated with FRONTLINE PLUS on 26 Mar 2018, for flea and tick prevention. On 31 Mar 2018, the dog was taken to a trip. Lack of efficacy suspected because the dog was infested by ticks and that should not happen. On 2 Apr 2018, the owner removed 43 ticks from the dog. UPDATE 5 APR 2018 – The pet owner was contacted and she reported that Leia, a 7.5 kg, female Pug (age unknown), was treated with one vial of FRONTLINE PLUS DOGS (size unknown) (018/17, Mar 2019), 'according to the product instructions' (topic, between the shoulder blades), by the reporter. Environment not treated. Current status unknown. There is no further information expected. |
| 06-Apr-2018 | UAE; 18BR002855; RJ; Brazil | **Species:** Feline<br>**Breed:** Persian (No Further Description)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.10 Year(s)<br>**Weight:** 3.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** FIPRONIL SPOT ON CAT;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 01-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Napoleão, a 3.1-year-old, 3.6 kg, male Persian cat, was treated with one vial of FRONTLINE SPOT-ON CAT (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, near 16 Mar 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation prior to FRONTLINE, environment treated with Butox and Triatox. The cat has contact with a dog of the neighborhood. Since FRONTLINE SPOT-ON CAT did not work, one vial of FRONTLINE PLUS CATS was applied to Napoleão on 31 Mar 2018. However, the product was not working as well as he expected too. It is unknown if FRONTLINE was applied to the cat in the past. 3 other cats of the same household that are also on FRONTLINE were reported on 18BR002856, 18BR002857 and 18BR002858. No further information is known. |
| 06-Apr-2018 | UAE; 18BR002856; RJ; Brazil | **Species:** Feline<br>**Breed:** Persian (No Further Description)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Month(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** FIPRONIL SPOT ON CAT;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 01-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Zeus, a 6-month-old, 2 kg, male Persian cat, was treated with one vial of FRONTLINE SPOT-ON CAT (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, near 16 Mar 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation prior to FRONTLINE, environment treated with Butox and Triatox. The cat has contact with a dog of the neighborhood. Since FRONTLINE SPOT-ON CAT did not work, one vial of FRONTLINE PLUS CATS was applied to Zeus on 31 Mar 2018. However, the product was not working as well as he expected too. It is unknown if FRONTLINE was applied to the cat in the past. 3 other cats of the same household that are also on FRONTLINE were reported on 18BR002855, 18BR002857 and 18BR002858. No further information is known. |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 06-Apr-2018 | UAE; 18BR002857; RJ; Brazil | **Species:** Feline **Breed:** Persian (No Further Description) **Sex:** M **Sex qualifier:** Unknown **Age:** 2.60 Year(s) **Weight:** 3.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL SPOT ON CAT; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 01-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Thor, a 2.6-year-old, 3.6 kg, male Persian cat, was treated with one vial of FRONTLINE SPOT-ON CAT (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, near 16 Mar 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation prior to FRONTLINE, environment treated with Butox and Triatox. The cat has contact with a dog of the neighborhood. Since FRONTLINE SPOT-ON CAT did not work, one vial of FRONTLINE PLUS CATS was applied to Thor on 31 Mar 2018. However, the product was not working as well as he expected too. It is unknown if FRONTLINE was applied to the cat in the past. 3 other cats of the same household that are also on FRONTLINE were reported on 18BR002855, 18BR002856 and 18BR002858. No further information is known. |
| 06-Apr-2018 | UAE; 18BR002858; RJ; Brazil | **Species:** Feline **Breed:** Persian (No Further Description) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.60 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** FIPRONIL SPOT ON CAT; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 01-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Roseli, a 2.6-year-old, 6 kg, female Persian cat, was treated with one vial of FRONTLINE SPOT-ON CAT (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, near 16 Mar 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation prior to FRONTLINE, environment treated with Butox and Triatox. The cat has contact with a dog of the neighborhood. Since FRONTLINE SPOT-ON CAT did not work, one vial of FRONTLINE PLUS CATS was applied to Roseli on 31 Mar 2018. However, the product was not working as well as he expected too. It is unknown if FRONTLINE was applied to the cat in the past. 3 other cats of the same household that are also on FRONTLINE were reported on 18BR002855, 18BR002856 and 18BR002857. No further information is known. |
| 06-Apr-2018 | UAE; 18BR002860; SP; Brazil | **Species:** Canine **Breed:** Mixed Breeds / various **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 06-Apr-2018* | 17 Day(s) | D-D | Suspected Lack of Effiaccy Claim: As reported by the pet owner, Belinha, a female mixed breed dog of 11 years old and unknown weight, received one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 20 Mar 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has not been treated and it is unknown if FL has previously been applied. There is another dog in this household that was treated with FL on 2 Feb 2018 and it has the same problem (See case 18BR002861). No further information is expected. |
| 06-Apr-2018 | UAE; 18BR002861; SP; Brazil | **Species:** Canine **Breed:** Mixed Breeds / various **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the** | N/A | 06-Apr-2018* | 17 Day(s) | D-D | Suspected Lack of Effiaccy Claim: As reported by the pet owner, Nick, a male mixed breed dog of 6 years old and unknown weight, received one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 2 Feb 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. There is another dog in this household that was treated with FL on 20 Mar 2018 and it has the same problem (See case 18BR002860). No further information is expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **product used ok?:** Unknown to Company | | | | | |
| 06-Apr-2018 | UAE; 18BR002862; RJ; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 06-Apr-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pule, a male small crossbred dog of 2 years old and 9 kg, received one vial of FRONTLINE PLUS S (FL) (lot and exp date are unknown, topical, neck - incorrect application), applied by the reporter on 29 Mar 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and fisrt application was not specified - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR002863 and 18BR002864. No further information is expected. |
| 06-Apr-2018 | UAE; 18BR002863; RJ; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 17.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 06-Apr-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Melissa, a female medium crossbred dog of 2 years old and 17.6 kg, received one vial of FRONTLINE PLUS M (FL) (lot and exp date are unknown, topical, neck - incorrect application), applied by the reporter on 29 Mar 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and fisrt application was not specified - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR002862 and 18BR002864. No further information is expected. |
| 06-Apr-2018 | UAE; 18BR002864; RJ; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 18 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 06-Apr-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Amora, a female medium crossbred dog of 7 years old and 18 kg, received one vial of FRONTLINE PLUS S (FL) (lot and exp date are unknown, topical, neck - incorrect application), applied by the reporter on 29 Mar 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and fisrt application was not specified - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR002862 and 18BR002863. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 06-Apr-2018 | UAE; 18BR002867; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 31-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Gaia, a 5-year-old approximately, 4 kg, female mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and between the shoulder blades, by the reporter, 1 week ago (30 Mar 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation prior to FL, environment treated with Butox, outdoor access. One other cat of the same household that is also on FL was reported on 18BR002868. There is a dog in the same household that was treated with an unknown product, but it is unknown if the pet is infested by fleas. No further information is available. |
| 06-Apr-2018 | UAE; 18BR002868; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 2.60 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 31-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Miria, a 2.6-year-old, 3 kg, female mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and between the shoulder blades, by the reporter, 1 week ago (30 Mar 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas . Flea infestation prior to FL, environment treated with Butox, outdoor access. One other cat of the same household that is also on FL was reported on 18BR002867. There is a dog in the same household that was treated with an unknown product, but it is unknown if the pet is infested by fleas. No further information is available. |
| 06-Apr-2018 | UAE; 18BR002869; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Maju, a 9-month-old, 5 kg, female Shih Tzu, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 15 Mar 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. There is one other dog in the same household that is also on FRONTLINE, but that dog is not infested. No further information is available. |
| 06-Apr-2018 | UAE; 18BR002871; MG; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 06-Apr-2018* | 22 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Francisco, 5 years old, 7 kilogram, canine, male, Mixed Breed received FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date, topically, between the shoulder blades), applied by the reporter on 15 Mar 2018. The owner complained about the lack of efficacy because he continues to see fleas in his pet. According to the owner, the animal already had fleas 1 week prior to treatment. The environment has not been treated. There is also a cat in the same household with similar problem (see case 18BR002872). No further information is available. |
| 06-Apr-2018 | UAE; 18BR002872; MG; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products** | N/A | 06-Apr-2018* | 22 Day(s) | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner, Frederico, 8 months old, 2.5 kilogram, feline, male, Mixed Breed received FRONTLINE SPOT-ON CAT (FL) (lot and exp date, topically, between the shoulder blades), applied by the reporter on 15 Mar 2018. The owner complained about the lack of efficacy |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Month(s)<br>**Weight:** 2.5 kg | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | because he continues to see fleas in his pet. According to the owner, the animal already had fleas 1 week prior to treatment. The environment has not been treated. There is also a cat in the same household with similar problem (see case 18BR002871). No further information is available. |
| 06-Apr-2018 | UAE; 18BR002873; MG; Brazil | **Species:** Canine<br>**Breed:** Pug<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 15.00 Month(s)<br>**Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 26-Mar-2018* | 27-Mar-2018* | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Maya, a female Pug of 15 months old and 9 kg, received, for the first time, one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 26 Mar 2018 (estimated date), for flea treatment. The pet was in good health prior to FL. One day after product application, the owner noticed a wound on her pet. In addition, Maya experienced itching, application site reddening and small lumps around the body. No vet care was provided and the symptoms are still ongoing. This is the extent of the information available. |
| 09-Apr-2018 | UAE; 18BR002877; MG; Brazil | **Species:** Canine<br>**Breed:** Great Dane<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 55 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 08-Apr-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Zeus, a 2-year-old, 55 kg, male Great Dane, was treated with one vial of FRONTLINE SPOT-ON DOGS XL (FL) (014/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 6 Apr 2018, for flea treatment. Lack of efficacy suspected because she discovered fleas on her dog yesterday (8 Apr 2018). Flea infestation one month prior to FL, environment treated with Triatox. It is unknown if FRONTLINE was applied to the dog in the past. There is no further information available. |
| 09-Apr-2018 | UAE; 18BR002879; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 05-Apr-2018 | 05-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Anubis, 1 years old, 7 kilogram, canine, male, Shih Tzu received for the first time FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date, topically, between the shoulder blades), applied by the reporter on 5 APR 2018, for flea treatment. According to the owner when FL was applied the application site became red and on the next morning the animal was scratching (06 APR 2018). the owner cut the hair in the region and cleaned it with a swab. The owner bathed the animal and start to treat the site of application with NEBACETIN ®. The animal was not taken to the veterinary and is recovering, only remaining the wound on the application site (06 APR 2018 – estimated date). No further information is available. |
| 09-Apr-2018 | UAE; 18BR002884; SP; Brazil | **Species:** Canine<br>**Breed:** Schnauzer<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No<br>(Treatment / | N/A | 09-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Alice, a female Schnauzer of 3 years old and 7 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, back and btw thw shoulder blades - incorrect application), applied by the reporter on 3 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. There is a cat in this household that was treated with another product against ectoparasites and it has no issue. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | vaccination program not respected) | | | | | |
| 04-Apr-2018 | UAE; 18BR002885; SP; Brazil | **Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 31-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, more than one cat received FRONTLINE, by the reporter, one week ago approximately. Lack of efficacy suspected because the cats were still scratching. FRONTLINE was applied in the past with no issues (dose frequency unknown and first application on date not specified - 1 Jan 2017 chosen at random). UPDATE 9 APR 2018 - The pet owner reported that Niquita, a 2-year-old, 4 kg, female Siamese, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (005/17, exp unknown), topic, base of skull and btw the shoulder blades, on 30 Mar 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation one month prior to FL, environment not treated, outdoor access denied. There's a dog in the same household that was treated with other company's product and is not infested by fleas; and one other cat that is also on FL was reported on 18BR002841. There is no further information expected. |
| 09-Apr-2018 | UAE; 18BR002886; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 35.00 Day(s) **Weight:** 500 gms | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 30-Mar-2018* | 09-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Ozzi, a male mixed breed cat of 35 days and 500 g, received, for the first time, FRONTLINE SPRAY (FL) (002/17 and unknown exp date, topical, abdome and back - incorrect application), applied by the reporter 10 days ago (30 Mar 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. There is another pet in this household with the same issue (see case 18BR002887). No further information is expected. UPDATE 4 MAY 2018 - The owner reported that FL was applied again around 9 Apr 2018. She applied all over the animal's body, but the pet remains infested by fleas. No further information is expected. |
| 09-Apr-2018 | UAE; 18BR002887; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 35.00 Day(s) **Weight:** 500 gms | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 30-Mar-2018* | 09-Apr-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Tufo, a male mixed breed cat of 35 days and 500 g, received FRONTLINE SPRAY (FL) (002/17 and unknown exp date, topical, abdome and back - incorrect application), applied by the reporter 10 days ago (30 Mar 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has been treated with deltamethrin. There is another pet in this household with the same issue (see case 18BR002886). No further information is expected. UPDATE 4 MAY 2018 - According to the owner, Tufo was treated with another product against fleas and he has no issue. No further information is expected. |
| 06-Apr-2018 | UAE; 18BR002889; PE; Brazil | **Species:** Canine **Breed:** Schnauzer **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 5.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products | 10-Mar-2018* | 06-Apr-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, Poni, a male Schnauzer of 12 years old and 5.8 kg, received, for the second time, one vial of FRONTLINE 'according to the weight of the animal' (FL) (unsubstantiated) (lot and exp date are unknown, topical, back and btw the shoulder blades), applied by the reporter 12 days ago (28 Mar 2018 - estimated date), for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. FL was applied for the first |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | time around 10 Mar 2018. The environment has been treated weekly with amitraz and deltamethrin. There is another dog in this household with the same issue (see case 18BR002890) and there is another dog that was treated with Bravecto® and it has no ectoparasite. No further information is expected. |
| 06-Apr-2018 | UAE; 18BR002890; PE; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 3.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 10-Mar-2018* | 06-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, Lilith, a female Yorkshire of 12 years old and 3.8 kg, received, for the second time, one vial of FRONTLINE (FL) 'according to the weight of the animal' (unsubstantiated) (lot and exp date are unknown, topical, back and btw the shoulder blades), applied by the reporter 12 days ago (28 Mar 2018 - estimated date), for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. FL was applied for the first time around 10 Mar 2018. The environment has been treated weekly with amitraz and deltamethrin. There is another dog in this household with the same issue (see case 18BR002889) and there is another dog that was treated with Bravecto® and it has no ectoparasite. No further information is expected. |
| 07-Apr-2018 | UAE; 18BR002898; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 200 gms | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 02-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one female cat of unknown signalment, recently rescued, was treated with FRONTLINE (unsubstantiated) (lot and exp unknown), by the reporter, one week ago approximately (presumed 31 Mar 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. This is the extent of the information available. UPDATE 12 APR 2018 – The pet owner was contacted and she reported that Renata, a 3-month-old, 200 G, female, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, 'last week' (1 Apr 2018 chosen at random). Flea infestation prior to FL, environment treated with Jimo. Another cat of the same household that is also on FL was reported on 18BR003011. There is no further information expected. |
| 09-Apr-2018 | UAE; 18BR002899; PR; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.50 Year(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Dec-2017* | 07-Mar-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Perrie, a 2.5-year-old, 4.5 kg, male mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (017/16, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on early Dec 2017 (1 Dec 2017 chosen at random) and on 7 Mar 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 1 week prior to FL, environment treated with Triatox. 3 other pets of the same household that are also on FL were reported on 18BR002900, 18BR002901 and 18BR002902. Another similar case reported on 18BR002903. There is no further information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 09-Apr-2018 | UAE; 18BR002900; PR; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 3.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Dec-2017* | 07-Mar-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Johnny, a 2-year-old, 3.8 kg, male mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (017/16, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on early Dec 2017 (1 Dec 2017 chosen at random) and on 7 Mar 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 1 week prior to FL, environment treated with Triatox. 3 other pets of the same household that are also on FL were reported on 18BR002899, 18BR002901 and 18BR002902. Another similar case reported on 18BR002903. There is no further information expected. |
| 09-Apr-2018 | UAE; 18BR002901; PR; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Month(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Dec-2017* | 07-Mar-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Menina, a 12-month-old, 7 kg, female mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (017/16, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on early Dec 2017 (1 Dec 2017 chosen at random) and on 7 Mar 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 1 week prior to FL, environment treated with Triatox. 3 other pets of the same household that are also on FL were reported on 18BR002899, 18BR002900 and 18BR002902. Another similar case reported on 18BR002903. There is no further information expected. |
| 09-Apr-2018 | UAE; 18BR002902; PR; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 01-Dec-2017* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Zack, a 7-month-old, 4 kg, male, crossbred dog, was treated with FRONTLINE SPRAY (FL) (017/16, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on early Dec 2017 (1 Dec 2017 chosen at random), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas . Flea infestation 1 week prior to FL, environment treated with Triatox. 3 other pets of the same household that are also on FL were reported on 18BR002899, 18BR002900 and 18BR002901. Another similar case reported on 18BR002903. There is no further information expected. |
| 09-Apr-2018 | UAE; 18BR002903; PR; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the** | N/A | 01-Jan-2014* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, one female dog of unknown signalment was treated with one vial of FRONTLINE 'pipette' (unsubstantiated) (lot and exp unknown), by the reporter, 'years ago' (1 Jan 2014 chosen at random). Lack of efficacy suspected however the owner did not mention what happened. This case was mentioned while the owner was reporting that her pets continued to have fleas post FRONTLINE SPRAY application (see 18BR002899 to 18BR002902). There is no further information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **product used ok?:** Unknown to Company | | | | | |
| 10-Apr-2018 | UAE; 18BR002906; SP; Brazil | **Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 15.00 Month(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dime, 15 months old, 3 kilogram, canine, male, Pinscher received FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date, topically, between the shoulder blades), applied by the reporter on 9 Apr 2018. The owner complained about the lack of efficacy because she continues to see fleas in her pet. According to the owner, the animal already had fleas 1 week prior to treatment. The environment has been treated with K-OTHRINE®. No further information is available. |
| 10-Apr-2018 | UAE; 18BR002910; MG; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-Apr-2018* | 2 Day(s) | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner, Tico, unknown age, 3 kilogram, canine, male, Poodle, received FRONTLINE SPRAY 100 mL (FL) (lot and exp date, topically, in the whole body), applied by the reporter on 8 Apr 2018. The owner complained about the lack of efficacy because he continues to see ticks in his pet. According to the owner, the animal already had ticks 1 month prior to treatment. The environment has not been treated. He already used FL in the past with no issues (date not specified). No further information is available. |
| 10-Apr-2018 | UAE; 18BR002914; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 9.3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 09-Apr-2018 | 09-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Snoop, a male small crossbred dog of 2 years old and 9.3 kg, received, for the first time, one vial of FRONTLINE SPOT-ON DOG S (FL) (004/17 and unknown exp date, topical, btw the shoulder blades), applied by the reporter on 9 Apr 2018 at 11 am, for flea/tick control. The pet was in good health prior to FL and he has history of food allergy. Some hours after product application, Snoop presented with itching. The symptom is still ongoing. No vet care was provided. This is the extent of the information available. |
| 09-Apr-2018 | UAE; 18BR002915; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 08-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Nick, a male Shih Tzu of 3 years old and 10 kg FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, neck and back - incorrect application), applied by the reporter on 29 Mar 2018. The owner believes that FL is not working because she continues to see fleas on her pet. Nick has flea allergic dermatitis and it has a lot of wounds. The surrounding environment has not been treated. FL has been applied every 2 months (first application was not provided - 1 Jan 2017 - chosen at random). No further information is expected. |
| 10-Apr-2018 | UAE; 18BR002920; RJ; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | N/A | 10-Apr-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bob, a 13-year-old, 23 kg, male, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG L (FL) (lot and exp unknown), |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 13.00 Year(s)<br>**Weight:** 23 kg | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | topic, head and between the shoulder blades, by the reporter, 1 month ago (10 Mar 2018), for flea treatment. Lack of efficacy suspected because the owner discovered one flea on her dog. Flea infestation few days prior to FL, environment treated with Talfon, outdoor access denied. No further information is available. |
| 10-Apr-2018 | UAE; 18BR002921; PR; Brazil | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Month(s)<br>**Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 04-Apr-2018 | 05-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Crux, a male Persian of 3 months old and 1.5 kg, received, for the first time, one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 4 Apr 2018, for flea treatment. The pet was in good health prior to FL. One day after product application, the pet started with discomfort and wound at the application site. In addition, he presented with redness and intense itching. The region was washed, but the symptoms are still ongoing. The pet was taken to the vet clinic and the vet prescribed an ointment, but the owner didn't use it. The vet has seen similar reactions, but the details were not provided. This is the extent of the information. |
| 10-Apr-2018 | UAE; 18BR002923; MG; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 26-Jan-2016* | 26-Feb-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Tarik, 4 years old, 6 kilogram, feline, male, Mixed Breed, received FRONTLINE PLUS CATS (FL) (lot 007/17 and exp date, topically, between the shoulder blades), applied by the reporter on 26 Mar 2018, for flea treatment. The owner complained about the lack of efficacy because he continues to see fleas in his pet. According to the owner, FL was applied on 26 Jan 2018 and on 26 Feb 2016 because he noticed fleas in his pet on february but the animal remains with fleas. The environment has been treated with BUTOX®, AMITRAZ® and K-OTHRINE®. He also has a dog in the same household treated with PROGRAM PLUS® and FRONTLINE PLUS® without fleas. No further information is available. |
| 10-Apr-2018 | UAE; 18BR002926; MG; Brazil | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 10.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 10-Apr-2018* | 13 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dobby, a male Poodle of 10 years old and 6 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 28 Mar 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The surrounding environment has been treated with deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 10-Apr-2018 | UAE; 18BR002928; | **Species:** Canine<br>**Breed:** Small | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT | N/A | 10-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Luna, a female small crossbred dog of 90 days old and 4.5 kg, |

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| | SP; Brazil | crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 90.00 Day(s)<br>**Weight:** 4.5 kg | | | | ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | received one vial of FRONTLINE SPOT-ON DOG S (FL) (004/17, unknown exp date, topical, btw the shoulder blades), applied by the veterinarian on 3 Apr 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasited. The surrounding environment has not been treated and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (see case 18BR002929). No further information is expected. |
| 10-Apr-2018 | UAE; 18BR002929; SP; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 90.00 Day(s)<br>**Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 10-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Thor, a male small crossbred dog of 90 days old and 4.5 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (004/17, unknown exp date, topical, btw the shoulder blades), applied by the veterinarian on 3 Apr 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasited. The surrounding environment has not been treated and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (see case 18BR002928). No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002931; MG; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 09-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Bob, a male Yorkshire of 5 years old and 3 kg, received FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, parts of the body - incorrect application), applied by the reporter on 6 Apr 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases were reported on 18BR002932, 18BR002933 and 18BR002934. On 11 Apr 2018, the pet owner was contacted and reported that NEXGARD was administered in the past on an unknown number of dogs and the product didn't work too (see case 18BR002955), but the details were not provided. No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002932; MG; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 09-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Tuntu, a male Yorkshire of approximately 2 years old and 3 kg, received FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, parts of the body - incorrect application), applied by the reporter on 6 Apr 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases were reported on 18BR002931, 18BR002933 and 18BR002934. On 11 Apr 2018, the pet owner was contacted and reported that NEXGARD was administered in the past on an unknown number of dogs and the product didn't work too (see case 18BR002955), but the details were not provided. No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002933; MG; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other | N/A | 09-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Bela, a female Yorkshire of approximately 3 years old and 3 kg, received FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, parts of the body - incorrect application), applied by the reporter on 6 Apr 2018, for tick treatment. Lack of efficacy is |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 3 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | suspected because the pet remains with ticks. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases were reported on 18BR002931, 18BR002932 and 18BR002934. On 11 Apr 2018, the pet owner was contacted and reported that NEXGARD was administered in the past on an unknown number of dogs and the product didn't work too (see case 18BR002955), but the details were not provided. No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002934; MG; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 09-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Rapunzel, a female Yorkshire of 5 years old and 3 kg, received FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, parts of the body - incorrect application), applied by the reporter on 6 Apr 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases were reported on 18BR002931, 18BR002932 and 18BR002933. On 11 Apr 2018, the pet owner was contacted and reported that NEXGARD was administered in the past on an unknown number of dogs and the product didn't work too (see case 18BR002955), but the details were not provided. No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002935; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 15.00 Month(s)<br>**Weight:** 3.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 11-Apr-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bigoduda, a female mixed breed cat of 15 months old and 3.6 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, back, neck and btw the shoulder blades - incorrect application), applied by the reporter on 9 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previouslye been applied. There is another cat in this household with the same issue (see case 18BR002936). No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002936; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 13.00 Month(s)<br>**Weight:** 2.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / | N/A | 11-Apr-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Filho, a female mixed breed cat of 3 years old and 2.6 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, back, neck and btw the shoulder blades - incorrect application), applied by the reporter on 9 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previouslye been applied. There is another cat in this household with the same issue (see case 18BR002935). No further information is expected. |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | vaccination program not respected) | | | | | |
| 11-Apr-2018 | UAE; 18BR002938; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 11-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dede, male Poodle of 8 years old and 8 kg, received one vial of FRONTLINE SPOT-DOG S (FL) (004/17 and unknown exp date, topical, neck and btw the shoulder blades - incorrect application), applied by the reporter on 2 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. There is another cat in this household with the same issue (see case 18BR002938). No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002939; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 11-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bibiu, male Poodle of 8 years old and 9 kg, received one vial of FRONTLINE SPOT-DOG S (FL) (004/17 and unknown exp date, topical, neck and btw the shoulder blades - incorrect application), applied by the reporter on 2 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. There is another cat in this household with the same issue (see case 18BR002938). No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002944; RJ; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 02-Apr-2018* | 1 Day(s) | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mutli, a 7-year-old, 5 kg, male crossbred dog, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, near 10 days ago (presumed 1 Apr 2018), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. 2 other dogs of the same household that are also on FL were reported on 18BR002945 and 18BR002946. No further information is available. |
| 11-Apr-2018 | UAE; 18BR002945; RJ; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | N/A | 02-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pig, a 6-year-old, 9 kg, female crossbred dog, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, near 10 days ago (presumed 1 Apr 2018), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. 2 other dogs of the same household that are also on FL were reported on 18BR002944 and 18BR002946. No further information |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Unknown to Company | | | | | is available. |
| 11-Apr-2018 | UAE; 18BR002946; RJ; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** M **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 02-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Amilton, a 13-year-old, 6 kg, male, Poodle, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, near 10 days ago (presumed 1 Apr 2018), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. 2 other dogs of the same household that are also on FL were reported on 18BR002944 and 18BR002945. No further information is available. |
| 12-Apr-2018 | UAE; 18BR002952; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 9.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 11-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Jade, a 3-year-old, 9.5 kg, female, crossbred dog, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 10 Apr 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have live ticks. Tick infestation less than one week prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FL was reported on 18BR002953. No further information is available. |
| 12-Apr-2018 | UAE; 18BR002953; SP; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** M **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 6.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 11-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Chubby, an 11-year-old, 6.2 kg, male, Poodle, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 10 Apr 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have live ticks. Tick infestation less than one week prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FL was reported on 18BR002952. No further information is available. |
| 12-Apr-2018 | UAE; 18BR002962; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 4.10 Year(s) **Weight:** 2.6 kg | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 12-Apr-2018* | 5 Day(s) | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner, Maple, a female Yorkshire of 4.1 years old and 2.6 kg, received one vial of FRONTLINE PLUS DOG S (FL) (018/17 and unknown exp date, topical, btw the shoulder blades), applied by the reporter on 7 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied . There is another dog in this household that was also treated with FL and it has no issue. No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002963; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | 01-Jul-2017* | 10-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, her dog was treated with FRONTLINE PLUS on 9 Apr 2018. Lack of efficacy suspected because the owner discovered fleas on the dog at the day of the report. UPDATE 12 APR 2018 – The owner was contacted and she reported that |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Age:** 2.00 Year(s)<br>**Weight:** 4.6 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | Valentina, a 2-year-old, 4.6 kg, female, Shih Tzu, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, for flea treatment. Flea infestation prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. UPDATE 8 MAY 2018 – The owner treated the environment with a product called MY PET® but continues to see fleas in her dog. She already used FL in the past with no issues (1 Jul 2017 – date chosen at random). No further information is available. |
| 12-Apr-2018 | UAE; 18BR002970; SP; Brazil | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 18.00 Month(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 05-Feb-2018* | 05-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, FRONTLINE SPRAY has been applied according to the label, however it was not working against fleas. UPDATE 12 APR 2018 – The pet owner was contacted and she reported that Pepe, an 18-month-old, 2 kg, female, Siamese cat, was treated with FRONTLINE SPRAY (FL) (004/16, Apr 2018), topic, whole body, by the reporter, for the past 2 months (last application last week – 5 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 2 months prior to FL, environment treated with Butox every 15 days. 5 other cats of the same household that are also on FL were reported on 18BR002971, 18BR002972, 18BR002973, 18BR002974 and 18BR002975. There is no further information expected. |
| 12-Apr-2018 | UAE; 18BR002971; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 05-Feb-2018* | 05-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, FRONTLINE SPRAY has been applied according to the label, however it was not working against fleas. UPDATE 12 APR 2018 – The pet owner was contacted and she reported that Nina, a 9-year-old, 5 kg, female, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (004/16, Apr 2018), topic, whole body, by the reporter, for the past 2 months (last application last week – 5 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 2 months prior to FL, environment treated with Butox every 15 days. 5 other cats of the same household that are also on FL were reported on 18BR002970, 18BR002972, 18BR002973, 18BR002974 and 18BR002975. There is no further information expected. |
| 12-Apr-2018 | UAE; 18BR002972; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 05-Feb-2018* | 05-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, FRONTLINE SPRAY has been applied according to the label, however it was not working against fleas. UPDATE 12 APR 2018 – The pet owner was contacted and she reported that Godo, a 7-year-old, 3.5 kg, female, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (004/16, Apr 2018), topic, whole body, by the reporter, for the past 2 months (last application last week – 5 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 2 months prior to FL, environment treated with Butox every 15 days. 5 other cats of the same household that are also on FL were reported on 18BR002970, 18BR002971, 18BR002973, 18BR002974 and 18BR002975. There is no further information expected. |
| 12-Apr-2018 | UAE; 18BR002973; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY | 05-Feb-2018* | 05-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, FRONTLINE SPRAY has been applied according to the label, however it was not working against fleas. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 2 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | UPDATE 12 APR 2018 – The pet owner was contacted and she reported that Guela, a 7-year-old, 2 kg, female, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (004/16, Apr 2018), topic, whole body, by the reporter, for the past 2 months (last application last week – 5 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 2 months prior to FL, environment treated with Butox every 15 days. 5 other cats of the same household that are also on FL were reported on 18BR002970, 18BR002971, 18BR002972, 18BR002974 and 18BR002975. There is no further information expected. |
| 12-Apr-2018 | UAE; 18BR002974; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 05-Feb-2018* | 05-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, FRONTLINE SPRAY has been applied according to the label, however it was not working against fleas. UPDATE 12 APR 2018 – The pet owner was contacted and she reported that Linda, a 5-year-old, 2 kg, female, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (004/16, Apr 2018), topic, whole body, by the reporter, for the past 2 months (last application last week – 5 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 2 months prior to FL, environment treated with Butox every 15 days. 5 other cats of the same household that are also on FL were reported on 18BR002970, 18BR002971, 18BR002972, 18BR002973 and 18BR002975. There is no further information expected. |
| 12-Apr-2018 | UAE; 18BR002975; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Month(s)<br>**Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 05-Feb-2018* | 05-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, FRONTLINE SPRAY has been applied according to the label, however it was not working against fleas. UPDATE 12 APR 2018 – The pet owner was contacted and she reported that Pepa, a 12-month-old, 1.5 kg, female, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (004/16, Apr 2018), topic, whole body, by the reporter, for the past 2 months (last application last week – 5 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 2 months prior to FL, environment treated with Butox every 15 days. 5 other cats of the same household that are also on FL were reported on 18BR002970, 18BR002971, 18BR002972, 18BR002973 and 18BR002974. There is no further information expected. |
| 12-Apr-2018 | UAE; 18BR002982; SP; Brazil | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 25 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 11-Apr-2018* | 19 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Charlie, a male large crossbred dog of 6 years old and 25 kg, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter 20 days ago (23 Mar 2018 - estimated date), for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites . The environment has been treated with deltamethrin. FL is applied every 75 days (first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR002983 to 18BR002987. There is one cat in this household that was not treated with FL and it has no issue. No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002983; SP; Brazil | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg) | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products** | 01-Jan-2017* | 11-Apr-2018* | 19 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Alemão, a male large crossbred dog of 4 years old and 25 kg, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter 20 days |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 25 kg | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | ago (23 Mar 2018 - estimated date), for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites . The environment has been treated with deltamethrin and FL is applied every 75 days (first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR002982, 18BR002984 to 18BR002987. There is one cat in this household that was not treated with FL and it has no issue . No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002984; SP; Brazil | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 11-Apr-2018* | 19 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Espoleta, a male large crossbred dog of 5 years old and 35 kg, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter 20 days ago (23 Mar 2018 - estimated date), for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites . The environment has been treated with deltamethrin and FL is applied every 75 days (first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR002982, 18BR002983, 18BR002985 to 18BR002987. There is one cat in this household that was not treated with FL and it has no issue. No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002985; SP; Brazil | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 11-Apr-2018* | 19 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Menina, a female large crossbred dog of 3 years old and 35 kg, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter 20 days ago (23 Mar 2018 - estimated date), for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites. The environment has been treated with deltamethrin and FL is applied every 75 days (first application was not provided - 1 Jan 2017 chosen at random). . Similar cases were reported on 18BR002982, 18BR002983, 18BR002984, 18BR002986 and 18BR002987. There is one cat in this household that was not treated with FL and it has no issue. No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002986; SP; Brazil | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 11-Apr-2018* | 19 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Neguinha, a female large crossbred dog of 5 years old and 25 kg, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter 20 days ago (23 Mar 2018 - estimated date), for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites . The environment has been treated with deltamethrin and FL is applied every 75 days (first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR002982 to 18BR002985 and 18BR002987. There is one cat in this household that was not treated with FL and it has no issue . No further information is expected. |
| 11-Apr-2018 | UAE; 18BR002987; SP; Brazil | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 20 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 01-Jan-2017* | 11-Apr-2018* | 19 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Cindy, a female large crossbred dog of 2 years old and 20 kg, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter 20 days ago (23 Mar 2018 - estimated date), for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites . The environment has been treated with deltamethrin and FL is applied every 75 days (first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR002982 to 18BR002986. There is one cat in this household |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Yes | | | | | that was not treated with FL and it has no issue. No further information is expected. |
| 12-Apr-2018 | UAE; 18BR002991; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 13-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via social media, FRONTLINE was not working to control a tick infestation. UPDATE 12 APR 2018 – The pet owner was contacted and she reported that Brisa, a 7-year-old, 10 kg, female, crossbred dog, was treated with one vial of FRONTLINE SPOT-ON DOGS (FL) (size, lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, one month ago (12 Mar 2018), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation 2 weeks prior to FL, environment treated every week with Butox. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FL was reported on 18BR002992. No further information is available. |
| 12-Apr-2018 | UAE; 18BR002992; SP; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 13-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via social media, FRONTLINE was not working to control of a tick infestation. UPDATE 12 APR 2018 – The pet owner was contacted and she reported that Pretinha, a 2-year-old, 6-8 kg, female, Poodle, was treated with one vial of FRONTLINE SPOT-ON DOGS (FL) (size, lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, one month ago (12 Mar 2018), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation 2 weeks prior to FL, environment treated every week with Butox. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FL was reported on 18BR002991. No further information is available. |
| 12-Apr-2018 | UAE; 18BR002997; PR; Brazil | **Species:** Canine **Breed:** Dachshund **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 4 | 4 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 18-Mar-2018* | 18-Mar-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 Dachshund dogs of unknown signalment were treated with 1 x 250 ml bottle of FRONTLINE SPRAY (FL) (lot and exp unknown), topic, back and chest, by the reporter, 25 days ago approximately (presumed 18 Mar 2018), for flea treatment. Lack of efficacy suspected because the dogs continued to have fleas. Then 1 x 100 ml bottle of FL was applied to the dogs 10 days ago approximately (presumed 2 Apr 2018), however the product is not working too. Flea infestation 1 month prior to FL, environment treated. There is no further information available. |
| 12-Apr-2018 | UAE; 18BR003004; MG; Brazil | **Species:** Canine **Breed:** Boxer **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | 31-Mar-2018* | 01-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lilith, a 4-month-old, 7 kg, female, Boxer, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, for the first time, near 31 Mar 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 5 days prior to FL, environment treated. No further information is available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Yes | | | | | |
| 12-Apr-2018 | UAE; 18BR003005; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 12-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Sofia, 6 years old, 5 kilogram, feline, female, Mixed Breed, received FRONTLINE SPOT-ON CAT (FL) (lot and exp date, topically, between the shoulder blades), applied by the reporter 9 days ago (3 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because she continues to see big and active fleas in her pet. According to the owner, the animal dont have contact with other animal or the street, she used FL as soon as she noticed fleas in her pet. In the past, she used REVOLUTION® and had no issues. There is also another cat in the same household with similar problem (see case 18BR003006). The environment has been treated with BUTOX®. No further information is available. |
| 12-Apr-2018 | UAE; 18BR003006; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 12-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Malu, 18 months old, 2.5 kilogram, feline, female, Mixed Breed, received FRONTLINE SPOT-ON CAT (FL) (lot and exp date, topically, between the shoulder blades), applied by the reporter 9 days ago (3 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because she continues to see big and active fleas in her pet. According to the owner, the animal dont have contact with other animal or the street, she used FL as soon as she noticed fleas in her pet. In the past, she used REVOLUTION® and had no issues. There is also another cat in the same household with similar problem (see case 18BR003005). The environment has been treated with BUTOX®. No further information is available. |
| 13-Apr-2018 | UAE; 18BR003008; CE; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 13-Apr-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Alef, a male medium crossbred dog of 6 months old and 15 kg, was treated with FRONTLINE SPRAY (FL) (015/16 and unknown exp date, topical, parts of the body - incorrect application), applied by the reporter on 9 Apr 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has not been treated and it is unknown if FL has previously been applied. No further information is expected. |
| 13-Apr-2018 | UAE; 18BR003009; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.50 Year(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination | 01-Jan-2017* | 01-Apr-2018 | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Fiona, a female medium crossbred dog of 2.5 years old and 15 kg, was treated with FRONTLINE SPRAY (FL) (004/16 and unknown exp date, topical, parts of the body), applied by the reporter on 20 Mar 2018, for tick control. Lack of efficacy is suspected because ticks were found since on 1 Apr 2018. The environment has been treated with fipronil. FL has been applied every 3 months with no issue (first application was not provided - 1 Jan 2017 chosen at random). No further information is expected. |

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| | | | | | | program not respected) | | | | | |
| 12-Apr-2018 | UAE; 18BR003011; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 02-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Rita, a 5-year-old, 4 kg, female, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 'last week' (1 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas . Flea infestation prior to FL, environment treated with Jimo. FRONTLINE was applied in the past with no issues (dose frequency unknown and first application on date not specified - 1 Jan 2017 chosen at random). One recently rescued cat of the same household that is also on FL was reported on 18BR002898. No further information is available. |
| 13-Apr-2018 | UAE; 18BR003019; RS; Brazil | **Species:** Canine **Breed:** Rottweiler **Sex:** F **Sex qualifier:** Unknown **Age:** 19.00 Month(s) **Weight:** 30 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 13-Apr-2018* | 24 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Luma, 19 months old, 30 kilogram, canine, female, Rottweiler, received FRONTLINE PLUS DOG L (FL) (lot and exp date, topically, between the shoulder blades), applied by the reporter on 20 Mar 2018, for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her pet . According to the owner, animal already had fleas 15 days prior to treatment. There are also another 2 dogs in the same household with similar problem (see case 18BR003020 and 18BR003021). The environment has been treated but the owner cannot remember the products name. No further information is available. |
| 13-Apr-2018 | UAE; 18BR003020; RS; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 17.00 Month(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 13-Apr-2018* | 24 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Mel, 17 months old, 9 kilogram, canine, female, Mixed Breed, received FRONTLINE PLUS DOG S (FL) (lot and exp date, topically, between the shoulder blades), applied by the reporter on 20 Mar 2018, for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her pet . According to the owner, animal already had fleas 15 days prior to treatment. There are also another 2 dogs in the same household with similar problem (see case 18BR003019 and 18BR003021). The environment has been treated but the owner cannot remember the products name. No further information is available. |
| 13-Apr-2018 | UAE; 18BR003021; RS; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 17.00 Month(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 13-Apr-2018* | 24 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Toffi, 17 months old, 6 kilogram, canine, male, Mixed Breed, received FRONTLINE PLUS DOG S (FL) (lot and exp date, topically, between the shoulder blades), applied by the reporter on 20 Mar 2018, for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her pet . According to the owner, animal already had fleas 15 days prior to treatment. There are also another 2 dogs in the same household with similar problem (see case 18BR003019 and 18BR003020). The environment has been treated but the owner cannot remember the products name. No further information is available. |

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| 13-Apr-2018 | UAE; 18BR003022; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 05-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, an unidentified male dog, received FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by the reporter 2 weeks ago (30 Mar 2018 – estimated date), for flea and tick treatment. The owner complained about the lack of efficacy because she continues to see fleas and ticks in her pet. The environmental conditions are unknown. No further information is available. UPDATE 16 APR 2018 – The pet owner was contacted and she reported that Rex, a 9-month-old, 15 kg approximately, male, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, on 4 Apr 2018. Flea and tick infestation 2 weeks prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. There is no further information expected. |
| 13-Apr-2018 | UAE; 18BR003023; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 3.4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 13-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Uili, 5 years old, 3.4 kilogram, canine, male, Yorkshire, received FRONTLINE SPRAY 100 mL (FL) (lot 004/17 and exp date unknown, topically, in the whole body), applied by the reporter on thursday (10 Apr 2018), for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her pet. According to the owner, animal already had fleas 1 month prior to treatment. There are also another 3 dogs in the same household with similar problem (see case 18BR003024 to 18BR003026). The environment has been treated with PULGOFF®. No further information is available. |
| 13-Apr-2018 | UAE; 18BR003024; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 13-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Julie 2 years old, 3 kilogram, canine, female, Yorkshire, received FRONTLINE SPRAY 100 mL (FL) (lot 004/17 and exp date unknown, topically, in the whole body), applied by the reporter on thursday (10 Apr 2018), for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her pet. According to the owner, animal already had fleas 1 month prior to treatment. There are also another 3 dogs in the same household with similar problem (see case 18BR003023, 18BR003025 and 18BR003026). The environment has been treated with PULGOFF®. No further information is available. |
| 13-Apr-2018 | UAE; 18BR003025; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 2.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 13-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Mickie, 6 months old, 2.7 kilogram, canine, male, Yorkshire, received FRONTLINE SPRAY 100 mL (FL) (lot 004/17 and exp date unknown, topically, in the whole body), applied by the reporter on thursday (10 Apr 2018), for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her pet. According to the owner, animal already had fleas 1 month prior to treatment. There are also another 3 dogs in the same household with similar problem (see case 18BR003023, 18BR003024 and 18BR003026). The environment has been treated with PULGOFF®. No further information is available. |
| 13-Apr-2018 | UAE; 18BR003026; SP; Brazil | **Species:** Canine **Breed:** Basset Hound **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / | N/A | 13-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Megui, 15 years old, 5 kilogram, canine, female, Basset, received FRONTLINE SPRAY 100 mL (FL) (lot 004/17 and exp date unknown, topically, in the whole body), applied by the reporter on thursday (10 Apr 2018), for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her pet. According to the owner, animal already had fleas 1 month prior |

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| | | Year(s)<br>**Weight:** 5 kg | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | to treatment. There are also another 3 dogs in the same household with similar problem (see case 18BR003023 to 18BR003025). The environment has been treated with PULGOFF®. No further information is available. |
| 13-Apr-2018 | UAE; 18BR003031; RJ; Brazil | **Species:** Canine<br>**Breed:** Poodle (Toy)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 16.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 29-Mar-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Thor, a 16-year-old, 5 kg, female, Poodle, was treated with FRONTLINE SPRAY (FL) (015/16, Nov 2018), topic, whole body, by the reporter, 15 days ago (29 Mar 2018), for tick treatment. Lack of efficacy suspected because the owner continues to find live attached ticks to his dog. Tick infestation prior to FL, environment treated with Cyperpour 15. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FL was reported on 18BR003032 No further information is available. |
| 13-Apr-2018 | UAE; 18BR003032; RJ; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 29-Mar-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, an 8-year-old, 15 kg, female, crossbred dog, was treated with FRONTLINE SPRAY (FL) (015/16, Nov 2018), topic, whole body, by the reporter, 15 days ago (29 Mar 2018), for tick treatment. Lack of efficacy suspected because the owner continues to find live attached ticks to his dog. Since he discovered one tick in the dog's ear and that did not die in 48 hours, TOPLINE (lot and exp unknown) was applied directly to the tick and then, it died. Tick infestation prior to FL, environment treated with Cyperpour 15. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FL was reported on 18BR003031 No further information is available. |
| 13-Apr-2018 | UAE; 18BR003036; SP; Brazil | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Month(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 04-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Luna, a 2-month-old, 2 kg, female, Siamese cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 3 Apr 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 5 days prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the cat in the past. No further information is available. |
| 16-Apr-2018 | UAE; 18BR003037; GO; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 05-Apr-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a 6 kg, female, crossbred dog (age unknown), was applied one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, back, by the reporter, on 3 Apr 2018, for tick treatment. Lack of efficacy suspected because the owner discovered live ticks on Belinha 2 days following product application, and she continued to have ticks since then. Tick infestation one day prior to FL, environment treated, outdoor access denied. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 16-Apr-2018 | UAE; 18BR003038; RJ; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 75.00 Day(s) **Weight:** 1.9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 03-Apr-2018 | 16-Apr-2018* | 13 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Theo, 75 days old, 1.9 kilogram, canine, male, Yorkshire, received FRONTLINE SPRAY 100 mL (FL) (lot 001/17 and exp date unknown, topically, in the whole body), applied by the reporter on 3 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because some fleas died but not all of them. According to the owner, animal already had when he acquired the pet. Theo does not go out to the streets. The environment has been treated but the owner does not know the products name. According to the owner, there are no fleas in the environment. No further information is available. |
| 15-Apr-2018 | UAE; 18BR003040; SP; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 15-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, an unidentified male dog, approximately 5 kilogram received FRONTLINE PLUS DOG® (FL) (lot, exp date, route and site of administration unknown), applied by the reporter on an unspecified date (14 Apr 2018 – date chosen at random), for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her pet. The environmental conditions are unknown. The owner also made a report regarding the product quality of FRONTLINE SPOT-ON DOGS S (see case 18BR002951). No further information is available. |
| 16-Apr-2018 | UAE; 18BR003041; SP; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 3.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 01-Apr-2018* | 0 Day(s) | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner, Abelhinha, a 4-month-old, 3.2 kg, female, crossbred Poodle, was treated with FRONTLINE SPRAY (FL) (002/17, exp unknown), topic, belly and near the tail, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation prior to FL, environment treated every week. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. UPDATE 24 APR 2018 - The owner called again and reported that Abelhinha remains with fleas. The pet doesn't have outdoor access. No further information is known. |
| 14-Apr-2018 | UAE; 18BR003042; SP; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 14-Apr-2018* | 26 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 2 female dogs of unknown signalment received one vial of FRONTLINE DOG M (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 19 Mar 2018, for tick treatment. Lack of efficacy is suspected because the pets remain with ticks. This is the extent of the information available. |
| 16-Apr-2018 | UAE; 18BR003045; | **Species:** Canine **Breed:** Yorkshire | 1 | 1 | 0 | **Product used:** FIPRONIL | 01-Jan-2016* | 01-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, an unknown BIAH product was not working as |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | SP; Brazil | Terrier<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 2 kg | | | | SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | well as it used to. UPDATE 16 APR 2018 – The owner was contacted and she reported that Bradok, a 4-year-old, 2 kg, male, Yorkshire Terrier, was treated with FRONTLINE SPRAY (FL) (018/16, Nov 2018), topic, location unknown, by the reporter, 15 days approximately (presumed 1 Apr 2018), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation prior to FL, environment treated with Butox at least once in a week. FRONTLINE was usually applied twice a year with no issues (first dose on date not specified – 1 Jan 2016 chosen at random). 3 other dogs that are also on FL were reported on 18BR003046, 18BR003047 and 18R003048. There are 2 cats in the same household that are on FL and not infested. There is no further information available. |
| 16-Apr-2018 | UAE; 18BR003046; SP; Brazil | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 25 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2016* | 01-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, an unknown BIAH product was not working as well as it used to. UPDATE 16 APR 2018 – The owner was contacted and she reported that Gordo, a 7-year-old, 25 kg, male, crossbred dog, was treated with FRONTLINE SPRAY (FL) (018/16, Nov 2018), topic, location unknown, by the reporter, 15 days approximately (presumed 1 Apr 2018), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation prior to FL, environment treated with Butox at least once in a week. FRONTLINE was usually applied twice a year with no issues (first dose on date not specified – 1 Jan 2016 chosen at random). 3 other dogs that are also on FL were reported on 18BR003045, 18BR003047 and 18R003048. There are 2 cats in the same household that are on FL and not infested. There is no further information available. |
| 16-Apr-2018 | UAE; 18BR003047; SP; Brazil | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 30 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2016* | 01-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, an unknown BIAH product was not working as well as it used to. UPDATE 16 APR 2018 – The owner was contacted and she reported that Hanna, a 5-year-old, 30 kg, female, Labrador Retriever, was treated with FRONTLINE SPRAY (FL) (018/16, Nov 2018), topic, location unknown, by the reporter, 15 days approximately (presumed 1 Apr 2018), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation prior to FL, environment treated with Butox at least once in a week. FRONTLINE was usually applied twice a year with no issues (first dose on date not specified – 1 Jan 2016 chosen at random). 3 other dogs that are also on FL were reported on 18BR003045, 18BR003046 and 18R003048. There are 2 cats in the same household that are on FL and not infested. There is no further information available. |
| 16-Apr-2018 | UAE; 18BR003048; SP; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 20 kg | 3 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2016* | 01-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, an unknown BIAH product was not working as well as it used to. UPDATE 16 APR 2018 – The owner was contacted and she reported that Safira, an 8-year-old, 20 kg, female, crossbred dog, was treated with FRONTLINE SPRAY (FL) (018/16, Nov 2018), topic, location unknown, by the reporter, 15 days approximately (presumed 1 Apr 2018), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation prior to FL, environment treated with Butox at least once in a week. FRONTLINE was usually applied twice a year with no issues (first dose on date not specified – 1 Jan 2016 chosen at random). 3 other dogs that are also on FL were reported on 18BR003045, 18BR003046 and 18R003047. There are 2 cats |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | in the same household that are on FL and not infested. There is no further information available. |
| 16-Apr-2018 | UAE; 18BR003049; SC; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the retail outlet via pet owner, Simon, a male Shih Tzu of approximately 2 years old and 6 kg, received one vial of FRONTLINE PLUS DOG S (FL) (008/16, Oct 2018, topical, btw the shoulder blades), applied by the reporter on 7 Apr 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites. It is unknown if FL has previously been applied and if the environment has been treated. Similar cases were reported on 18BR003050 and 18BR003051. further information is available. |
| 16-Apr-2018 | UAE; 18BR003050; SC; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the retail outlet via pet owner, Laila, a female Shih Tzu of 4 years old and 5 kg, received one vial of FRONTLINE PLUS DOG S (FL) (008/16, Oct 2018, topical, btw the shoulder blades), applied by the reporter on 7 Apr 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites. It is unknown if FL has previously been applied and if the environment has been treated. Similar cases were reported on 18BR003049 and 18BR003051. No further information is available. |
| 16-Apr-2018 | UAE; 18BR003052; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Month(s) **Weight:** 1.1 kg | 3 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 14-Apr-2018 | 16-Apr-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Belinha, 1 month old, 1.1 kilogram, canine, female, Shih Tzu, received FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the head and on the animal´s butt) applied by the owner on 14 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her animal. According to the owner, animal already had fleas when she came from the countryside. The environment has not been treated. The owner also had another dog and 1 cat and they were both treated with FL and have no issues. No further information is available. |
| 14-Apr-2018 | UAE; 18BR003054; RS; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 3 | 3 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown | 01-Jun-2017* | 14-Apr-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, 3 unidentified dogs, received FRONTLINE® (FL) (lot, exp date, route and site of administration unknown) applied by the owner on an unspecified date (12 Apr 2018 – date chosen at random), for an unknown reason. The owner complained about the lack of efficacy because FL only had effect during the first day, on the second day, her dogs were scratching. According to the owner, she already used FL in the past with no issues (01 Jun 2017 – date chosen at random). The environment has been treated with an unspecified product. The owner uses FL monthly. No further information is available. |

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| | | | | | | to Company | | | | | |
| 14-Apr-2018 | UAE; 18BR003059; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | 01-Jan-2017* | 14-Apr-2018* | 25 Day(s) | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, Vitoria, a female Poodle of 11 years old and 7 kg, received an unknown dose of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades, dose was fractionated - low dose), applied by the reporter on 20 Mar 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with Butox® every 4 months. In addition, the pet has flea allergic dermatitis and FL has been applied monthly (first application was not provided - 1 Jan 2017 chosen at random). There is another dog in this household with the same issue (see case 18BR003060). No further information is expected. |
| 14-Apr-2018 | UAE; 18BR003060; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 14-Apr-2018* | 25 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, Belinha, a female small crossbred dog of 11 years old and 10 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 20 Mar 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with Butox® every 4 months. In addition, the pet has flea allergic dermatitis and FL has been applied monthly (first application was not provided - 1 Jan 2017 chosen at random). There is another dog in this household with the same issue (see case 18BR003059). No further information is expected. |
| 16-Apr-2018 | UAE; 18BR003062; SP; Brazil | **Species:** Canine **Breed:** Dalmatian **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Jan-2012* | 01-Jan-2017* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, one female Dalmatian, 5 years old approximately, had been treated with FRONTLINE (unsubstantiated) (lot and exp unknown), by the reporter, for the past 5 years (first and last doses on dates not specified – 1 Jan 2012 and 1 Jan 2017 chosen at random). Lack of efficacy mentioned, however details were not provided. This case was reported while the owner was reporting another SLOE case (see 18BR003061). There is no further information expected. |
| 16-Apr-2018 | UAE; 18BR003063; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 04-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Cindy, a 9-year-old, 4.5 kg, female, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG S (FL) (001/17, exp unknown), topic, between the shoulder blades, by the reporter, on 3 Mar 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 3 months prior to FL, environment treated. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FRONTLINE was reported on 18BR003064. No further information is available. |

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| 16-Apr-2018 | UAE; 18BR003064; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 4.50 Year(s) **Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 04-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Kiara, a 4.5-year-old, 14 kg, female, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, between the shoulder blades, by the reporter, on 3 Mar 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 3 months prior to FL, environment treated. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FRONTLINE was reported on 18BR003063. No further information is available. |
| 17-Apr-2018 | UAE; 18BR003067; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 20-Mar-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Margarida, 3 years old, 2 kilogram, feline, female, Mixed Breed, received FRONTLINE PLUS CATS (FL) (lot and exp date unknown, according to the owner, applied as described in label – topically, between the shoulder blades), applied by the reporter on the second fortnight of March (20 Mar 2018 – date chosen at random), for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her pet. The environment has not been treated. The animal does not go out the house. No further information is available. |
| 17-Apr-2018 | UAE; 18BR003068; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Nina, 10 years old, 4.5 kilogram, feline, female, Mixed Breed, received FRONTLINE SPOT-ON CAT (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 16 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because he found new fleas in his pet. According to the owner, the animal already had fleas 1 and a half month prior to treatment. The environment has not been treated. The owner believes that fleas may be being brought by pigeons No further information is available. |
| 17-Apr-2018 | UAE; 18BR003071; SP; Brazil | **Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 2.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Princesa, 10 years old, 2.8 kilogram, feline, female, Siamese, received FRONTLINE SPOT-ON CAT (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 5 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because she continued to find fleas in her pet. According to the owner, the animal already had fleas 10 days prior to treatment. The environment has not been treated. There are another 3 cats in the same household with similar problem (see cases 18BR003072 to 18BR003074). No further information is available. |
| 17-Apr-2018 | UAE; 18BR003072; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products | N/A | 17-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Maurice, 16 months old, 3.5 kilogram, feline, male, Mixed Breed, received FRONTLINE SPOT-ON CAT (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 5 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because she continued to find fleas in her pet. According to the owner, the animal already had fleas 10 |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** 16.00 Month(s)<br>**Weight:** 3.5 kg | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | days prior to treatment. The environment has not been treated. There are another 3 cats in the same household with similar problem (see cases 18BR003071, 18BR003073 and 18BR003074). No further information is available. |
| 17-Apr-2018 | UAE; 18BR003073; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 16.00 Month(s)<br>**Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 17-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Alfredo, 16 months old, 3.5 kilogram, feline, male, Mixed Breed, received FRONTLINE SPOT-ON CAT (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 5 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because she continued to find fleas in her pet. According to the owner, the animal already had fleas 10 days prior to treatment. The environment has not been treated. There are another 3 cats in the same household with similar problem (see cases 18BR003071, 18BR003072 and 18BR003074). No further information is available. |
| 17-Apr-2018 | UAE; 18BR003074; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 17-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Sebastian, 2 years old, 3 kilogram, feline, male, Mixed Breed, received FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 5 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because she continued to find fleas in her pet. According to the owner, the animal already had fleas 10 days prior to treatment. The environment has not been treated. There are another 3 cats in the same household with similar problem (see cases 18BR003071 to 18BR003073). Sebastian is the only cat in the house who walks on the streets. No further information is available. |
| 17-Apr-2018 | UAE; 18BR003075; SP; Brazil | **Species:** Canine<br>**Breed:** Maltese<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 13.00 Year(s)<br>**Weight:** 32 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 17-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dime, a male Maltese of 13 years old and 32 kg, received one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 14 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. No further information is expected. |
| 17-Apr-2018 | UAE; 18BR003079; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Month(s)<br>**Weight:** 1.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 17-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a female Shih Tzu of 1 month old and 1.1 kg, received FRONTLINE SPRAY (FL) (015/16 and unknown exp date, topical, whole body), applied by the reporter on 14 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. There are two more animals in this household that were also treated with FL and they have no issue. No further information is expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 17-Apr-2018 | UAE; 18BR003082; SP; Brazil | **Species:** Feline **Breed:** Persian (No Further Description) **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 03-Apr-2018 | 17-Apr-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Sony, 4 years old, 5 kilogram, feline, male, Persian, received for the first time FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 3 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because she continued to find fleas in her pet. According to the owner, the animal already had fleas 2 weeks prior to treatment. The environment has been treated with K-OTHRINE. The cat used to have access to the garage but since he got fleas he does not go there. The owner used to administrate an unidentified product for flea treatment. No further information is available. |
| 17-Apr-2018 | UAE; 18BR003083; SP; Brazil | **Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sheldon, a 7-year-old, 8 kg, male, Jack Russell Terrier, was treated with one vial of FRONTLINE PLUS DOG S (FL) (014/17, Feb 2019), topic, base of skull and btw the shoulder blades, by the reporter, 2 days ago (15 Apr 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation one day prior to FL, environment treated with Fleegard. FRONTLINE TRI-ACT was applied in the past with no issues. It is unknown if FRONTLINE PLUS was applied to the dog in the past. One other dog of the same household that is also on FL was reported on 18BR003084. No further information is available. |
| 17-Apr-2018 | UAE; 18BR003084; SP; Brazil | **Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Shower, a 10-year-old, 9 kg, male, Jack Russell Terrier, was treated with one vial of FRONTLINE PLUS DOG S (FL) (014/17, Feb 2019), topic, base of skull and btw the shoulder blades, by the reporter, 2 days ago (15 Apr 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation one day prior to FL, environment treated with Fleegard. FRONTLINE TRI-ACT was applied in the past with no issues. It is unknown if FRONTLINE PLUS was applied to the dog in the past. One other dog of the same household that is also on FL was reported on 18BR003083. No further information is available. |
| 17-Apr-2018 | UAE; 18BR003085; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 17-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Floquinho, a male Poodle of 10 years old and 4 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 11 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The surrounding environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). No further information is expected. |
| 17-Apr-2018 | UAE; 18BR003087; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON | N/A | 10-Mar-2018 | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Maya, a 3-year-old, 1.5 kg, female, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 45 days ago (3 Mar 2018), for flea treatment. All fleas |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 1.5 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | died, however lack of efficacy is suspected because the cat was infested by fleas again 1 week post product application. Flea infestation 8 months prior to FL, environment treated with K-Othrine. It is unknown if FRONTLINE was applied to the cat in the past. No further information is available. |
| 15-Apr-2018 | UAE; 18BR003096; SP; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Month(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2018* | 11-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 2 dogs of unknown signalment were treated each one with one vial of FRONTLINE PLUS DOGS (size, lot and exp unknown), by the reporter, on 10 Apr 2018, for tick treatment. Lack of efficacy suspected because the dogs continued to have ticks . FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). This is the extent of the information available. UPDATE 18 APR 2018 - The pet owner was contacted and reported that Filó, a female Lhasa Apso of 6 months old and 4 kg, received FL PLUS DOG S (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 10 Apr 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with deltamethrin. The other dog was reported on 18BR003125. No further information is expected. |
| 17-Apr-2018 | UAE; 18BR003104; SP; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 17-Apr-2017* | 16 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Tati, a female Lhasa Apso of 3 years old and 7 kg, received one vial of FRONTLINE PLUS DOG (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter one year ago (1 Apr 2017 – chosen at random), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . It is unknwon if the environment has been treated and if FL has previously been applied. There is another dog in this household with the same issue (see case 18BR003105). The owner also complained about the lack of efficacy of NEXGARD (see cases 18BR003101, 18BR003102 and 18BR003103). No further information is expected. |
| 17-Apr-2018 | UAE; 18BR003105; SP; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 17-Apr-2017* | 16 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Snoop, a male Lhasa Apso of 8 years old and 4 kg, received one vial of FRONTLINE PLUS DOG (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter one year ago (1 Apr 2017 – chosen at random), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . It is unknwon if the environment has been treated and if FL has previously been applied. There is another dog in this household with the same issue (see case 18BR003104). The owner also complained about the lack of efficacy of NEXGARD (see cases 18BR003101, 18BR003102 and 18BR003103). No further information is expected. |
| 16-Apr-2018 | UAE; 18BR003108; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON | 19-Mar-2018* | 10-Apr-2018* | 5 Day(s) | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female cat of unknown signalment was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), by the reporter, twice, on dates not specified (1 Mar 2018 and 1 Apr 2018 chosen at random), for flea treatment. Lack of efficacy |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex qualifier:** Unknown **Age:** 15.00 Month(s) **Weight:** 5 kg | | | | **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | suspected because the cat continued to have fleas. Environment treated. The owner also mentioned has applied FRONTLINE (unsubstantiated) (lot and exp unknown), however it is unknown if to the same pet. This is the extent of the information available. UDPATE 20 APR 2018 - The owner was contacted and reported that Clara, a female mixed breed cat of 15 months old and 5 kg, was treated, for the second time, with FL (007/17 and unknown exp date), topical, btw the shoulder blades, applied by the reporter around 15 days ago (5 Apr 2018 - estimated date), for flea treatment. The environment has been treated with an unknown product. FL was applied for the first time around 1 month ago (19 Mar 2018 - estimated date). The reporter also complained about the lack of efficacy of FL SPRAY in another cat (see case 18BR003166). No further information is expected. |
| 18-Apr-2018 | UAE; 18BR003109; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 18-Apr-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Lulu, unknown age, 4.5 kilogram, feline, male, Mixed Breed, received FRONTLINE SPOT-ON CAT (FL) (lot 015/16 and exp date unknown, topically, between the shoulder blades), applied by the reporter on 14 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because she continued to find fleas in her pet. According to the owner, the animal already had fleas 1 week prior to treatment. The animal used to walk on the street. The environment has not been treated and it is unknown if FL was applied in the past. No further information is available. UPDATE 15 MAY 2018 - The owner contact to say that she treated the environment but her animal, remains with fleas. No further information is available. |
| 18-Apr-2018 | UAE; 18BR003116; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Oct-2017* | 18-Apr-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Alemão, a male mixed breed cat of 'less than 2 kg' and unknown age, was treated with FRONTLINE SPOT-ON CAT (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 2 weeks ago (4 Apr 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and FL was applied in the past with no issue (1 Oct 2017 - estimated date). There are two dogs in this household with similar issue (See cases 18BR003117 and 18BR003118). No further information is expected. |
| 18-Apr-2018 | UAE; 18BR003117; RS; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 20 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Oct-2017* | 18-Apr-2018* | 2 Week(s) | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner, Espaique, a male medium crossbred dog of 6 years old and 20 kg, was treated with FRONTLINE SPOT-ON DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 2 weeks ago (4 Apr 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet is itching himself. No ectoparasites were reported. The environment has not been treated and FL was applied in the past with no issue (1 Oct 2017 - estimated date). There are two animals in this household with similar issue (See cases 18BR003116 and 18BR003118). No further information is expected. |
| 18-Apr-2018 | UAE; 18BR003118; RS; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products | 01-Oct-2017* | 18-Apr-2018* | 2 Week(s) | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bela, a female small crossbred dog of 1 year old and 5 kg, was treated with FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 2 weeks ago (4 Apr 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 5 kg | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | with fleas. The environment has not been treated and FL was applied in the past with no issue (1 Oct 2017 - estimated date). There are two animals in this household with similar issue (See cases 18BR003116 and 18BR003117). No further information is expected. |
| 18-Apr-2018 | UAE; 18BR003119; SP; Brazil | **Species:** Canine<br>**Breed:** Maltese<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 11-Apr-2017* | 18-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Bolti, 7 years old, 7 kilogram, canine, male, Maltese, received FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 1 week ago (11 Apr 2018 – estimated date), for flea control. The owner complained about the lack of efficacy because she found fleas alive in her pet. According to the owner, she uses FL monthly for more than a year (first application on 11 Apr 2017 - estimated date). The environment has been treated with BUTOX®. According to the owner, the veterinarian and the shopkeeper, told her the product would also protect the environment. There is also a cat in the same household with similar problem (see case 18BR003120). No further information is available. |
| 18-Apr-2018 | UAE; 18BR003120; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 11-Apr-2017* | 18-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Beatriz, 1 year old, 4 kilogram, feline, female, Mixed Breed, received FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 1 week ago (11 Apr 2018 – estimated date), for flea control. The owner complained about the lack of efficacy because she found fleas alive in her pet. According to the owner, she uses FL monthly for more than a year (first application on 11 Apr 2017 - estimated date). The environment has been treated with BUTOX®. According to the owner, the veterinarian and the shopkeeper, told her the product would also protect the environment. There is also a dog in the same household with similar problem (see case 18BR003119). No further information is available. |
| 15-Apr-2018 | UAE; 18BR003125; SP; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Month(s)<br>**Weight:** 5.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2018* | 18-Apr-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bud, a male Lhasa Apso of 6 months old and 5.5 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 10 Apr 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with deltamethrin and FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2018 chosen at random). The other dog was reported on 18BR003096. No further information is expected. |
| 18-Apr-2018 | UAE; 18BR003127; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** 16.00 Month(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the** | 01-Aug-2017* | 18-Apr-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Luma, 16 months old, 2 kilogram, canine, unknown sex, Yorkshire, received FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 4 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her animal. According to the owner, the animal always had fleas since she got it 1 year ago. The environment has been treated with an unknown product. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Aug 2017 - chosen at random). The animal does not leave the |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **product used ok?:** Yes | | | | | house. The owner also complained about the lack of efficacy of FRONTLINE SPRAY® (see case 18BR003128). No further information is available. |
| 18-Apr-2018 | UAE; 18BR003128; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** U **Sex qualifier:** Unknown **Age:** 16.00 Month(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 18-Apr-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Luma, 16 months old, 2 kilogram, canine, unknown sex, Yorkshire, received FRONTLINE SPRAY (FL) (lot, exp date, route and site of administration unknown), applied by the reporter on an unspecified date (4 Feb 2018 – date chosen at random), for flea treatment. The owner complained about the lack of efficacy because initially the fleas number decreased but after awhile they returned. According to the owner, the animal always had fleas since she got it 1 year ago. The environment has been treated with an unknown product and it is unknown if FL was applied in the past. The animal does not leave the house. The owner also complained about the lack of efficacy of FRONTLINE PLUS DOG S (see case 18BR003127). No further information is available. |
| 18-Apr-2018 | UAE; 18BR003132; SC; Brazil | **Species:** Feline **Breed:** Persian (No Further Description) **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 06-Apr-2017* | 18-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Miguel, 4 years old, 5 kilogram, feline, male, Persian, received FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 6 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because after FL he saw, around, 5 fleas in his pet. According to the owner, he applies FL monthly in his pets since a long time (6 Apr 2017 – date chosen at random) and treats the environment every 45 days. The environment has been treated with COLOSSO®. The owner also has another 2 cats and 3 dogs presenting a similar condition (see cases 18BR003133 to 18BR003137). No further information is available. |
| 18-Apr-2018 | UAE; 18BR003133; SC; Brazil | **Species:** Feline **Breed:** Persian (No Further Description) **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 06-Apr-2017* | 18-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Leonardo, 2 years old, 5 kilogram, feline, male, Persian, received FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 6 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because after FL he saw, around, 5 fleas in his pet. According to the owner, he applies FL monthly in his pets since a long time (6 Apr 2017 – date chosen at random) and treats the environment every 45 days. The environment has been treated with COLOSSO®. The owner also has another 2 cats and 3 dogs presenting a similar condition (see cases 18BR003132 and 18BR003134 to 18BR003137). No further information is available. |
| 18-Apr-2018 | UAE; 18BR003134; SC; Brazil | **Species:** Feline **Breed:** Persian (No Further Description) **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 06-Apr-2017* | 18-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Mel, 8 years old, 5 kilogram, feline, female, Persian, received FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 6 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because after FL he saw, around, 5 fleas in his pet. According to the owner, he applies FL monthly in his pets since a long time (6 Apr 2017 – date chosen at random) and treats the environment every 45 days. The environment has been treated with COLOSSO®. The owner also has another 2 cats and 3 dogs presenting a similar condition (see cases 18BR003132, 18BR003133 and 18BR003135 to 18BR003137). No further information is available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 18-Apr-2018 | UAE; 18BR003135; SC; Brazil | **Species:** Canine **Breed:** Chowchow **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 22 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 06-Apr-2017* | 18-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Boby, 5 years old, 22 kilogram, canine, male, ChowChow, received FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 6 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because after FL he saw, around, 5 fleas in his pet. According to the owner, he applies FL monthly in his pets since a long time (6 Apr 2017 – date chosen at random) and treats the environment every 45 days. The environment has been treated with COLOSSO®. The owner also has another 3 cats and 2 dogs presenting a similar condition (see cases 18BR003132 to 18BR003134, 18BR003136 and 18BR003137). No further information is available. |
| 18-Apr-2018 | UAE; 18BR003136; SC; Brazil | **Species:** Canine **Breed:** Chowchow **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 22 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 06-Apr-2017* | 18-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Vima, 1 year old, 22 kilogram, canine, female, ChowChow, received FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 6 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because after FL he saw, around, 5 fleas in his pet. According to the owner, he applies FL monthly in his pets since a long time (6 Apr 2017 – date chosen at random) and treats the environment every 45 days. The environment has been treated with COLOSSO®. The owner also has another 3 cats and 2 dogs presenting a similar condition (see cases 18BR003132 to 18BR003135 and 18BR003137). No further information is available. |
| 18-Apr-2018 | UAE; 18BR003137; SC; Brazil | **Species:** Canine **Breed:** Chowchow **Sex:** F **Sex qualifier:** Unknown **Age:** 30.00 Month(s) **Weight:** 23 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 06-Apr-2017* | 18-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Lara, 30 months old, 23 kilogram, canine, female, ChowChow, received FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 6 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because after FL he saw, around, 5 fleas in his pet. According to the owner, he applies FL monthly in his pets since a long time (6 Apr 2017 – date chosen at random) and treats the environment every 45 days. The environment has been treated with COLOSSO®. The owner also has another 3 cats and 2 dogs presenting a similar condition (see cases 18BR003132 to 18BR003136). No further information is available. |
| 18-Apr-2018 | UAE; 18BR003138; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / | 01-Nov-2017* | 07-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a 6-month-old, 10 kg, female, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, from the base of skull to near the tail, by the reporter, on 6 Mar 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas and scratching. Since then the owner has applied FL every 15 days, but Mel is still scratching because of flea infestation. 'Last month', FRONTLINE PLUS DOG M started being applied to the dog (21 Mar 2018 chosen at random). FL was usually applied every month since Nov 2017 with no issues. Flea infestation 20 days prior to FL, environment not treated. There is no further information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | vaccination program not respected) | | | | | |
| 18-Apr-2018 | UAE; 18BR003139; PR; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Month(s) **Weight:** 13 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 01-Dec-2017* | 24-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Keithy, a 12-month-old, 13 kg, female, crossbred dog, was treated with one vial of FRONTLINE (unsubstantiated) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 23 Mar 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation one week prior to FL, environment not treated. FRONTLINE was usually applied in the past with no issues (1 Dec 2017 - chosen at random). One other dog of the same household that is also on FRONTLINE was reported on 18BR003140. No further information is available. |
| 18-Apr-2018 | UAE; 18BR003140; PR; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 01-Jan-2018* | 24-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Davi, a 3-year-old, 5 kg, male, Shih Tzu, was treated with one vial of FRONTLINE (unsubstantiated) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 23 Mar 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation one week prior to FL, environment not treated. FRONTLINE was usually applied in the past with no issues (1 Jan 2018 - chosen at random). One other dog of the same household that is also on FRONTLINE was reported on 18BR003139. No further information is available. |
| 19-Apr-2018 | UAE; 18BR003143; MG; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Month(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jul-2017* | 19-Apr-2018* | 4 Week(s) 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Paulinho, a 12-month-old, 7 kg, male, Shih Tzu, was treated with FRONTLINE SPRAY (FL) (002/17, exp unknown), topic, back and paws, by the reporter, almost 1 month ago (17 Mar 2018 chosen at random), for flea prevention. Lack of efficacy suspected because the dog is currently infested by fleas. FRONTLINE was applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jul 2017 chosen at random). Environment treated with Butox. 2 cats in the household have outdoor access. Those cats and one other dog of the same household are also on FL and are reported on 18BR003144, 18BR003145 and 18BR003146. No further information is available. |
| 19-Apr-2018 | UAE; 18BR003144; MG; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 5.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the** | 01-Jul-2017* | 19-Apr-2018* | 4 Week(s) 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bebel, a 3-year-old, 5.5 kg, female, crossbred dog, was treated with FRONTLINE SPRAY (FL) (002/17, exp unknown), topic, back and paws, by the reporter, almost 1 month ago (17 Mar 2018 chosen at random), for flea prevention. Lack of efficacy suspected because the dog is currently infested by fleas. FRONTLINE was applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jul 2017 chosen at random). Environment treated with Butox. 2 cats in the household have |

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| | | | | | | **product used ok?:** No (Treatment / vaccination program not respected) | | | | | outdoor access. Those cats and one other dog of the same household are also on FL and are reported on 18BR003143, 18BR003145 and 18BR003146. No further information is available. |
| 19-Apr-2018 | UAE; 18BR003145; MG; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jul-2017* | 17-Mar-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Zeus, an 18-month-old, 5 kg, male, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (002/17, exp unknown), topic, back and paws, by the reporter, almost 1 month ago (17 Mar 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation few days prior to FL, environment treated with Butox, outdoor access. One other cat and 2 dogs of the same household that are also on FL were reported on 18BR003143, 18BR003144 and 18BR003146. No further information is available. |
| 19-Apr-2018 | UAE; 18BR003146; MG; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Month(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jul-2017* | 17-Mar-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lion, a 12-month-old, 5 kg, male, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (002/17, exp unknown), topic, back and paws, by the reporter, almost 1 month ago (17 Mar 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation few days prior to FL, environment treated with Butox, outdoor access. One other cat and 2 dogs of the same household that are also on FL were reported on 18BR003143, 18BR003144 and 18BR003145. No further information is available. |
| 19-Apr-2018 | UAE; 18BR003147; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 13-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Açaí, a 15-year-old, 15 kg, female, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 12 Apr 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. UDPATE 23 APR 2018 - According to the vet, the product was applied on 14 Apr 2018 and the pet remains with ticks. No further information is expected. |
| 19-Apr-2018 | UAE; 18BR003153; RJ; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products | N/A | 19-Apr-2018* | 4 Week(s) 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Kiara, a female medium crossbred dog of 3 years old and 15 kg, was treated with FRONTLINE SPRAY (FL) (004/16 and unknown exp date, topical, whole body), applied by the reporter on 18 Mar 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with |

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| | | Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 15 kg | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 19-Apr-2018 | UAE; 18BR003157; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 17-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Thor, a 5-year-old, 5 kg, male, Yorkshire Terrier, was treated with one vial of FRONTLINE PLUS DOG S (FL) (001/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 16 Mar 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 2 weeks prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 18-Apr-2018 | UAE; 18BR003158; SP; Brazil | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 02-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one 4-year-old cat (other signalment unknown), was treated with one vial of FRONTLINE 'for cats' (unsubstantiated) (lot and exp unknown), by the reporter, on date not specified (1 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. This is the extent of the information available. |
| 17-Apr-2018 | UAE; 18BR003161; RS; Brazil | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 3 | 3 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2017* | 17-Apr-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 3 dogs of unknown signalment, received FRONTLINE PLUS (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 8 Apr 2018, for flea/tick control. Lack of efficacy is suspected because live ticks were found on the dogs. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). No further information is available. |
| 20-Apr-2018 | UAE; 18BR003162; -; Brazil | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 02-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, one dog, 4 kg (other signalment unknown), was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), by the reporter, on date not specified (1 Apr 2018 chosen at random). Lack of efficacy suspected, however it is unknown what happened. The owner refused to provide any additional information. There is no further information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 19-Apr-2018 | UAE; 18BR003163; SP; Brazil | **Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 19-Apr-2010* | 06-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, an unidentified canine, male, Maltese received 01 pipette of FRONTLINE PLUS® (FL) (lot 018/17 and exp date MAR 2019, route and site of administration unknown), applied by the reporter on an unspecified date (19 Mar 2018 – date chosen at random), for flea treatment. The owner complained about the lack of efficacy because he continues to find fleas in his pet. According to the owner, he bought FL less than 2 months ago and already applied a second pipette without results. The environmental condition are unknown. The owner has used FL for over 8 years (19 Apr 2010 – estimated date). No further information is available. UPDATE 23 APR 2018 – The pet owner was contacted and he reported that Luigi, 10 years old, 5 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL), topic, base of skull and btw the shoulder blades, on 5 Apr 2018, for flea prevention. Lack of efficacy suspected because the owner has discovered fleas on Luigi post product application. Environment not treated, outdoor access twice per day. There is no further information expected. |
| 19-Apr-2018 | UAE; 18BR003164; SP; Brazil | **Species:** Feline **Breed:** Persian (No Further Description) **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 19-Apr-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, an unidentified male feline received 01 pipette of FRONTLINE SPOT-ON CAT (FL) (lot, and exp date, route and site of administration unknown), applied by the reporter on 11 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because the number of fleas are increasing. The environmental condition are unknown. No further information is available. UPDATE 7 MAY 2018 - The pet owner contacted BIAH and reported that Eros, a male Persian of 12 years old and 6 kg, was treated with one vial of FL, topically and between the shoulder blades. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). The pet remains with fleas. No further information is expected. |
| 19-Apr-2018 | UAE; 18BR003166; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 05-Mar-2018* | 15-Apr-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Elis, a female mixed breed cat of approximately 2 months old and 1 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (002/17, unknown exp date, topical, whole body), applied by the reporter around 15 days ago (5 Apr 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product. Similar case was reported on 18BR003108. No further information is expected. |
| 19-Apr-2018 | UAE; 18BR003167; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | 26-Feb-2018* | 26-Feb-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, 2 unidentified, female canines, received FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by an unknown person on an unspecified date (19 Mar 2018 – date chosen at random), for an unknown reason. The owner complained about the lack of efficacy of FL. The environmental condition are unknown. No further information is available. UPDATE 26 APR 2018 - The owner was contacted and reported that Jade, a female Yorkshire of 4 years old and 4.5 kg, received, for the first time, FRONTLINE 'pipette' (unsubstantiated) (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 2 months ago (26 Feb 2018 - estimated |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Unknown to Company | | | | | date), for flea treatment. Lack of efficacy suspected because Jade had fleas and she was itching (due to fleas). The environment has not been treated. NEXGARD was given and the pet is currently free of fleas. A similar case was reported on 18BR003269. There is also a cat in this household treated with a flea collar. No further information is expected. |
| 20-Apr-2018 | UAE; 18BR003169; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 18 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jul-2012* | 07-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, FRONTLINE was applied to her pet 2 weeks ago approximately. Lack of efficacy suspected because the pet is still infested by fleas. FRONTLINE has been applied for the past 6 years with no issues. UPDATE 20 APR 2018 - Mel, a 6-year-old, 18 kg, female, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 2 weeks ago (6 Apr 2018), for flea treatment. Flea infestation 2 weeks prior to FL, environment not treated. FRONTLINE was applied to the dog in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jul 2012 chosen at random). There is no further information available. |
| 23-Apr-2018 | UAE; 18BR003172; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 30.00 Month(s) **Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 23-Apr-2018 | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Maria Francisca, 30 months old, 1.5 kilogram, feline, female, Mixed Breed, received FRONTLINE PLUS CATS (FL) (lot 005/17 and exp date unknown, topically, between the shoulder blades ), applied by the reporter 30 days ago (23 Mar 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because after FL he continues to see the cat scratching . The environment has not been treated. No further information is available. |
| 23-Apr-2018 | UAE; 18BR003173; SP; Brazil | **Species:** Canine **Breed:** Border Collie **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 23-Apr-2018* | 19 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Sindi, 6 years old, 15 kilogram, canine, female, Border Collie, received FRONTLINE PLUS DOG M (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the reporter on 4 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because her dogs continues with fleas . According to the owner, the animal already had fleas 1 months prior to treatment. The environment has not been treated. There are 2 other dogs in the same household with similar problem ( see cases 18BR003174 and 18BR003175). No further information is available. |
| 23-Apr-2018 | UAE; 18BR003174; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous | N/A | 23-Apr-2018* | 19 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Saimon, 2 to 3 years old, 6 kilogram, canine, male, Shih Tzu, received FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the reporter on 4 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because her dogs continues with fleas . According to the owner, the animal already had fleas 1 months prior to treatment. The environment has not been treated. There are 2 other dogs in the same household with similar problem ( see cases 18BR003173 and 18BR003175). No further information is |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **Was the product used ok?:** Yes | | | | | available. |
| 23-Apr-2018 | UAE; 18BR003175; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 23-Apr-2018* | 19 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Mel, 2 to 3 years old, 6 kilogram, canine, female, Poodle, received FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 4 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because her dogs continues with fleas. According to the owner, the animal already had fleas 1 months prior to treatment. The environment has not been treated. There are 2 other dogs in the same household with similar problem ( see cases 18BR003173 and 18BR003174). No further information is available. |
| 20-Apr-2018 | UAE; 18BR003176; RJ; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Month(s) **Weight:** 3.2 kg | 10 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 20-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Raquel, a 12-month-old, 3.2 kg, female, Shih Tzu, was treated with FRONTLINE SPRAY (FL) (005/16, exp unknown), topic, from the base of skull to the tail, by the reporter, on 19 Apr 2018, for tick treatment. FL was applied the same way to more 9 dogs on that day. On the following day (20 Apr 2018), Raquel's eyes were closed. One eye was cloudy. The owner believes that Raquel had contact to the other dogs and her eyes might have touched their backs. She was not taken to the vet, but the owner was dripping some eye drops. The signs are still ongoing. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 20-Apr-2018 | UAE; 18BR003177; SP; Brazil | **Species:** Canine **Breed:** Schnauzer (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 8.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 20-Oct-2008* | 20-Apr-2018* | 30 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Aaron, a 10-year-old, 8.5 kg, male, Schnauzer, was treated with one vial of FRONTLINE PLUS DOG S (FL) (001/17 and exp date unknown), by the reporter, 30 days ago approximately (presumed 21 Mar 2018). Following product application, the dog presented with 'liver issues'. Other details were not provided. No further information is available. UPDATE 24 APR 2018 – The owner said that Aaron was taken to the veterinary to run some tests and the values of ALT were changed. The owner used FL for 2 months and during this period the ALT values increased. Two DVMs believed that the increase in ALT values might have been caused by FL administration but were not sure about that assumption. A third DVM was contacted and informed that FL is not absorbed in the bloodstream. The owner does not believe that FL caused the changes in the enzyme levels. The owner is a FL user for some time, applying the product every 40 to 60 days (20 Oct 2008 – date chosen at random). No further information is available. |
| 23-Apr-2018 | UAE; 18BR003179; SP; Brazil | **Species:** Canine **Breed:** Dachshund **Sex:** F **Sex qualifier:** Unknown **Age:** 2.50 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other | N/A | 23-Apr-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Dachshund of 2.5 years old and approximately 7 kg, received one vial of FRONTLINE PLUS DOG S (FL) (018/17 and unknown exp date, topical, btw the shoulder blades), applied by the reporter 2 weeks ago (9 Apr 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 7 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (See case 18BR003180). No further information is expected. UPDATE 26 APR 2018 - The pet owner still believes that FL is not working, because the dog continued to have fleas. There is no further information expected. |
| 23-Apr-2018 | UAE; 18BR003180; SP; Brazil | **Species:** Canine<br>**Breed:** Dachshund<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.50 Year(s)<br>**Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 23-Apr-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Maick, a male Daschund of 2.5 years old and 7 kg, received one vial of FRONTLINE PLUS DOG S (FL) (018/17 and unknown exp date, topical, btw the shoulder blades), applied by the reporter 2 weeks ago (9 Apr 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (See case 18BR003179). No further information is expected. UPDATE 26 APR 2018 - The pet owner still believes that FL is not working, because the dog continued to have fleas. There is no further information expected. |
| 23-Apr-2018 | UAE; 18BR003181; SP; Brazil | **Species:** Feline<br>**Breed:** Persian (No Further Description)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Year(s)<br>**Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2012* | 23-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bili, a 12-year-old, 8 kg, male, Persian, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (021/16, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 22 Apr 2018 afternoon, for flea treatment. Lack of efficacy suspected because the cat is still infested by fleas and scratching. Flea infestation one day prior to FL, environment treated. FRONTLINE was applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2012 chosen at random). Other cat of the same household that is also on FL was reported on 18BR003182. No further information is available. |
| 23-Apr-2018 | UAE; 18BR003182; SP; Brazil | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2012* | 23-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Fifi, a 7-year-old, 2 kg, female, Siamese cat, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (021/16, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 22 Apr 2018 afternoon, for flea treatment. Lack of efficacy suspected because the cat is still infested by fleas and scratching. Flea infestation one day prior to FL, environment treated. FRONTLINE was applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2012 chosen at random). Other cat of the same household that is also on FL was reported on 18BR003181. No further information is available. |
| 20-Apr-2018 | UAE; 18BR003184; RJ; Brazil | **Species:** Canine<br>**Breed:** Maltese<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 3.9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 20-Apr-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Julie, a female Maltese of 3 years old and 3.9 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 10 Apr 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The surrounding environment has not been treated and FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). No further information is expected. |

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| 23-Apr-2018 | UAE; 18BR003185; GO; Brazil | **Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 45 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Mar-2018* | 18-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Tila, a 5-year-old, 45 kg, female, Pit Bull, was treated with one vial of FRONTLINE PLUS DOG XL (FL) (010/16, Nov 2018), topic, base of skull and btw the shoulder blades, by the reporter, on 17 Apr 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation prior to FL, environment treated with Triatox. FRONTLINE was applied once on date not specified (1 Mar 2018 chosen at random). There are other dogs in the same household, however it is unknown if they were treated with any tick killer product. The owner mentioned that the vial of FL contained less product than usual (PQC reported on 18BR003186), but it was still applied to the dog. No further information is available. |
| 23-Apr-2018 | UAE; 18BR003188; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 13-Apr-2018 | 23-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sindi, a female Shih Tzu of 3 years old and 6 kg, received, for the second time, one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 20 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was applied for the first time on 13 Apr 2018. No further information is expected. |
| 23-Apr-2018 | UAE; 18BR003191; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 22-Mar-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Magali, unknown age, 3 kilogram, feline, female, Mixed Breed, received FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 15 Mar 2018, for flea treatment. The owner complained about the lack of efficacy because after FL she continues to see fleas in her cat. According to the owner, animal already had fleas 1 week prior to treatment. The environment has been treated with K-OTHRINE®. No further information is available. UPDATE 24 APR 2018 - According to the owner via social media, fleas were found on her pet on 22 Apr 2018. No further information is known. UPDATE 25 APR 2018 – According to the owner via social media, lack of efficacy is suspected because her cat was infested by fleas again one week post product application. The owner was contacted and she reported that the amount of fleas on Magali has decreased. The environment was treated twice. There is no further information expected. |
| 24-Apr-2018 | UAE; 18BR003202; SP; Brazil | **Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 870 gms | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | N/A | 24-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sofia, a female Pinscher of 4 months old and 870 grams, received FRONTLINE SPRAY (FL) (003/17, unknown exp date, topical, whole body), applied by the reporter on 23 Apr 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites. The environment has not been treated and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (see case 18BR003203). No further information is expected. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **ok?:** Yes | | | | | |
| 24-Apr-2018 | UAE; 18BR003203; SP; Brazil | **Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 24-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Djuli, a female small crossbred dog of 1 year old and 4.5 kg, received FRONTLINE SPRAY (FL) (003/17, unknown exp date, topical, whole body), applied by the reporter on 23 Apr 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites. The environment has not been treated and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (see case 18BR003202). No further information is expected. |
| 24-Apr-2018 | UAE; 18BR003204; SP; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 32 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 24-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Hulk, 6 years old, 32 kilogram, canine, male, Mixed Breed, received FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 7 days ago (17 Apr 2018 – estimated date), for tick control. The owner complained about the lack of efficacy because her dogs got ticks. The environment has been treated with BUTOX®. There are 2 other dogs in the same household with similar problem (see cases 18BR003205 and 18BR003206). Near the owner´s house there is a river with capybaras. No further information is available. |
| 24-Apr-2018 | UAE; 18BR003205; SP; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 28 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 24-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Popo, 9 years old, 28 kilogram, canine, male, Mixed Breed, received FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 7 days ago (17 Apr 2018 – estimated date), for tick control. The owner complained about the lack of efficacy because her dogs got ticks. The environment has been treated with BUTOX®. There are 2 other dogs in the same household with similar problem (see cases 18BR003204 and 18BR003206). Near the owner´s house there is a river with capybaras. No further information is available. |
| 24-Apr-2018 | UAE; 18BR003206; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 24-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Pupy, 11 years old, 9 kilogram, canine, female, Poodle, received FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 7 days ago (17 Apr 2018 – estimated date), for tick control. The owner complained about the lack of efficacy because her dogs got ticks. The environment has been treated with BUTOX®. There are 2 other dogs in the same household with similar problem (see cases 18BR003204 and 18BR003205). Near the owner´s house there is a river with capybaras. No further information is available. |
| 24-Apr-2018 | UAE; 18BR003207; SP; Brazil | **Species:** Feline **Breed:** Turkish Angora **Sex:** F **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / | 04-Feb-2017* | 24-Apr-2018* | 20 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Nina, 18 months old, 4 kilogram, feline, female, Turkish Angora, received FRONTLINE PLUS CATS (FL) (lot 004/17 and exp date unknown, topically, between the shoulder blades), applied by the reporter 20 days ago (4 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because after FL she continues to see fleas in her cat. The environment has been treated with BUTOX®. The owner already used FL for the first time 1 year ago (4 Apr 2017 – estimated date) |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | and it does not work too. No further information is available. |
| 24-Apr-2018 | UAE; 18BR003208; SP; Brazil | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 24-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Poodle of 8 years old and 8 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 17 Apr 2018, for flea control. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. No further information is expected. |
| 24-Apr-2018 | UAE; 18BR003209; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 2.3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 24-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Brenda, 2 years old, 2.3 kilogram, canine, female, Yorkshire, received FRONTLINE PLUS DOG S (FL) (lot 018/17 and exp date unknown, topically, between the shoulder blades), applied by the reporter on 21 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because his dogs continues with fleas. The environment has been treated with BUTOX®. There are 2 other dogs in the same household with similar problem ( see cases 18BR003210 and 18BR003211). No further information is available. |
| 24-Apr-2018 | UAE; 18BR003210; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Month(s)<br>**Weight:** 1.9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 24-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Rilari, 9 months old, 1.9 kilogram, canine, female, Yorkshire, received FRONTLINE PLUS DOG S (FL) (lot 018/17 and exp date unknown, topically, between the shoulder blades), applied by the reporter on 21 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because his dogs continues with fleas. The environment has been treated with BUTOX®. There are 2 other dogs in the same household with similar problem ( see cases 18BR003209 and 18BR003211). No further information is available. |
| 24-Apr-2018 | UAE; 18BR003211; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Month(s)<br>**Weight:** 1.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | N/A | 24-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Jhulie, 9 months old, 1.1 kilogram, canine, female, Yorkshire, received FRONTLINE PLUS DOG S (FL) (lot 018/17 and exp date unknown, topically, between the shoulder blades), applied by the reporter on 21 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because his dogs continues with fleas. The environment has been treated with BUTOX®. There are 2 other dogs in the same household with similar problem ( see cases 18BR003209 and 18BR003210). No further information is available. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Yes | | | | | |
| 24-Apr-2018 | UAE; 18BR003215; -; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 24-Apr-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, an unknown dog, received FRONTLINE SPOT-ON DOGS® (FL) (lot, exp date, route and site of administration unknown), applied by the reporter on an unspecified date (20 Apr 2018 – date chosen at random), for tick treatment. The owner complained about the lack of efficacy because his dog continues with ticks. The environmental condition are unknown. No further information is available. |
| 24-Apr-2018 | UAE; 18BR003217; SP; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 24-Apr-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lola, a female Lhasa Apso of 2 years old and 5 kg, received one vial of FRONTLINE PLUS DOG S (FL) (018/17 and unknown exp date, topical, btw the shoulder blades), applied by the reporter 10 days ago (14 Apr 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and FL was also applied 30 days ago (24 Mar 2018 - estimated date). The dose frequency is unknown and the first application was not provided - 1 Jan 2017 chosen at random. There is another dog in this household that was also treated with FL and it has no ectoparasite. No further information is expected. |
| 24-Apr-2018 | UAE; 18BR003220; RJ; Brazil | **Species:** Canine **Breed:** Shiba Inu **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 3.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 24-Apr-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Snoop, 3 months old, 3.1 kilogram, canine, female, Shih Tzu, received FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 1 month ago (24 Mar 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because her dog continued with fleas. The environment has not been treated. The reporter got the animal around 20 days ago No further information is available. |
| 24-Apr-2018 | UAE; 18BR003221; MG; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 24-Apr-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Billy, 2 years old, 5 kilogram, canine, male, Yorkshire, received FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 24 Mar 2018, for flea and tick treatment. The owner complained about the lack of efficacy because his dog continues with fleas and ticks. According to the owner the animal already had parasites 1 week prior to treatment. The environment has not been treated. No further information is available. |
| 24-Apr-2018 | UAE; 18BR003223; PR; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | N/A | 24-Apr-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sasha, a female medium crossbred dog of 7.5 years old and 18 kg, received one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 16 Apr 2018, for tick treatment. Lack of efficacy |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Unknown<br>**Age:** 7.50 Year(s)<br>**Weight:** 18 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | is suspected because the pet remains with ticks. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 22-Apr-2018 | UAE; 18BR003224; SP; Brazil | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 09-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one dog of unknown signalment was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), 'according to the product label' (topic, btw the shoulder blades), by the reporter, 2 weeks ago (8 Apr 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas . Flea infestation prior to FL, environment treated. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FRONTLINE was reported on 18BR003225. No further information is available. |
| 22-Apr-2018 | UAE; 18BR003225; SP; Brazil | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 09-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one dog of unknown signalment was treated with one vial of FRONTLINE PLUS DOG L (FL) (lot and exp unknown), 'according to the product label' (topic, btw the shoulder blades), by the reporter, 2 weeks ago (8 Apr 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas . Flea infestation prior to FL, environment treated. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FRONTLINE was reported on 18BR003224. No further information is available. |
| 25-Apr-2018 | UAE; 18BR003226; SP; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 13 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** FIPRONIL SPOT ON DOG;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 16-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dom, a 3-year-old, 13 kg, male, Lhasa Apso, was treated with one vial of FRONTLINE SPOT-ON DOGS M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 20 days ago (5 Apr 2018), for flea prevention. Lack of efficacy suspected because the dog is currently infested by fleas . Since FL did not work, one vial of FRONTLINE PLUS DOG M (lot and exp unknown) was applied to Dom 10 days ago (15 Apr 2018), the same was as FL. However, the dog continued to have fleas . Environment not treated. FRONTLINE was applied in the past with no issues (dose frequency unknown and first application on date not specified – 1 Jan 2017 chosen at random). There is no further information available. |
| 25-Apr-2018 | UAE; 18BR003228; BA; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Month(s)<br>**Weight:** 4.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous | N/A | 25-Apr-2018* | 20 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Kenay, a male Shih Tzu of 4 months old and 4.1 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (009/17 and unknown exp date, topical, btw the shoulder blades), applied by the reporter on 5 Apr 2018, for tick control. Lack of efficacy is suspected because the pet has ticks. The environment has not been treated and it is unknown if FL has previously been applied . No further information is expected. |

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| | | | | | | **Was the product used ok?:** Yes | | | | | |
| 25-Apr-2018 | UAE; 18BR003236; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 12 kg | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 25-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Milka, a 12-year-old, 12 kg, female, crossbred dog, was treated with 1 vial of FRONTLINE SPOT PLUS DOG M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, less than 15 days ago (13 Apr 2018 chosen at random), for flea prevention. Lack of efficacy suspected because the dog is currently infested by fleas. Environment not treated, outdoor access denied. It is unknown if FRONTLINE was applied to the dog in the past. 2 other dogs of the same household that are also on FRONTLINE were reported on 18BR003237 and 18BR003238. There is a cat in the household that is also on FRONTLINE but not infested by fleas. No further information is available. |
| 25-Apr-2018 | UAE; 18BR003237; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 5 kg | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose) | N/A | 25-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a 15-year-old, 5 kg, female, crossbred dog, was treated with 1 vial of FRONTLINE SPOT PLUS DOG M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, less than 15 days ago (13 Apr 2018 chosen at random), for flea prevention. Lack of efficacy suspected because the dog is currently infested by fleas. Environment not treated, outdoor access denied. It is unknown if FRONTLINE was applied to the dog in the past. 2 other dogs of the same household that are also on FRONTLINE were reported on 18BR003236 and 18BR003238. There is a cat in the household that is also on FRONTLINE but not infested by fleas. No further information is available. |
| 25-Apr-2018 | UAE; 18BR003238; SP; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 25 kg | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 25-Apr-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Milu, a 13-year-old, 25 kg, female, crossbred dog, was treated with FRONTLINE (unsubstantiated) (dose, lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, less than 15 days ago (13 Apr 2018 chosen at random), for flea prevention. Lack of efficacy suspected because the dog is currently infested by fleas. Environment not treated, outdoor access denied. It is unknown if FRONTLINE was applied to the dog in the past. 2 other dogs of the same household that are also on FRONTLINE were reported on 18BR003236 and 18BR003237. There is a cat in the household that is also on FRONTLINE but not infested by fleas. No further information is available. |
| 23-Apr-2018 | UAE; 18BR003239; SP; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used** | 01-Jul-2017* | 25-Mar-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one female dog of unknown signalment was treated with FRONTLINE PLUS (unsubstantiated) (lot and exp unknown), by the reporter, on 24 Mar 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas . Similar issue reported in the past (see 17BR005061). This is the extent of the information available. |

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| | | | | | | **ok?:** Unknown to Company | | | | | |
| 25-Apr-2018 | UAE; 18BR003242; SP; Brazil | **Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 25-Apr-2018* | 16 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Babalu, 8 years old, 1.5 kilogram, canine, female, Pinscher, received FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 9 Apr 2018, for tick control. The owner complained about the lack of efficacy because her dog got ticks. According to the owner she noticed ticks in the environment, but the animal had none prior to treatment. The environment has been treated but the owner cannot remember the product´s name. No further information is available. |
| 25-Apr-2018 | UAE; 18BR003247; SP; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 22 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 25-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Akiles, 11 years old, 22 kilogram, canine, male, Mixed Breed, received FRONTLINE SPOT-ON DOGS M (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 1 week ago (18 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because her dog continued with fleas. According to the owner,animal already had fleas 1 years prior to treatment. The environment has been treated with alcohol, other unidentified products and also a vacuum cleaner. The animal already lost the hair in his tail due to the scratching. The owner also uses the vacuum cleaner in the animal. No further information is available. |
| 24-Apr-2018 | UAE; 18BR003252; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 16.00 Year(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2015* | 12-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via social media, 3 dogs were treated with FRONTLINE, however they are infested by fleas. UPDATE 26 APR 2018 – The owner was contacted and she reported that Cindy, a 16-year-old, 2 kg, female, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 15 days ago (11 Apr 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 10 days prior to FL, FRONTLINE is applied every 2 months since date not specified (1 Jan 2015 chosen at random, environment not treated, outdoor access on weekends. The other 2 dogs of the household were reported on 18BR003253 and 18BR003254. No further information is available. |
| 24-Apr-2018 | UAE; 18BR003253; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2015* | 12-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via social media, 3 dogs were treated with FRONTLINE, however they are infested by fleas. UPDATE 26 APR 2018 – The owner was contacted and she reported that Sofia, a 10-year-old, 5 kg, female, Shih Tzu, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 15 days ago (11 Apr 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 10 days prior to FL, FRONTLINE is applied every 2 months since date not specified (1 Jan 2015 chosen at random, environment not treated, outdoor access on weekends. The other 2 dogs of the household were reported on 18BR003252 and 18BR003254. No further information is available. |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 24-Apr-2018 | UAE; 18BR003254; SP; Brazil | **Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2015* | 12-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via social media, 3 dogs were treated with FRONTLINE, however they are infested by fleas. UPDATE 26 APR 2018 – The owner was contacted and she reported that Joly, a 6-year-old, 15 kg, female, Cocker Spaniel, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 15 days ago (11 Apr 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 10 days prior to FL, FRONTLINE is applied every 2 months since date not specified (1 Jan 2015 chosen at random, environment not treated, outdoor access on weekends, flea allergy dermatitis. The other 2 dogs of the household were reported on 18BR003252 and 18BR003253. No further information is available. |
| 24-Apr-2018 | UAE; 18BR003255; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 16.00 Year(s) **Weight:** 5.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 24-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Ted, 16 years old, 5.6 kilogram, canine, male, Poodle, received FRONTLINE PLUS DOG S (FL) (lot 001/17 and exp date unknown, topically, between the shoulder blades), applied by the reporter on 18 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because her dog continued to have fleas . According to the owner, animal already had fleas 16 days prior to treatment. The environment has been treated with BUTOX®. The owner also complained about a suspected adverse event (see case 18BR003256). There is also another dog in the same household who lives separated and was treated with another product (no information provided). The owner already used FRONTLINE TRI-ACT® in the past with no issues. No further information is available. |
| 24-Apr-2018 | UAE; 18BR003256; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 16.00 Year(s) **Weight:** 5.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 18-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the owner, Ted, 16 years old, 5.6 kilogram, canine, male, Poodle, received FRONTLINE PLUS DOG S (FL) (lot 001/17 and exp date unknown, topically, between the shoulder blades), applied by the reporter on 18 Apr 2018, for flea treatment. According to the owner, after a few hours, the animal had vomiting and loss of appetite. The animal was taken to the veterinary who treated Ted with medications for the liver. The owner said the animal did not had oral contact with FL. The animal recovered (24 Apr 2018 - date chosen at random) but still scratching due to fleas. The owner also complained about the lack of efficacy of FL (see case 18BR003255). The owner already used FRONTLINE TRI-ACT® in the past with no issues. No further information is available. |
| 26-Apr-2018 | UAE; 18BR003257; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 4 kg | 4 | 4 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jul-2017* | 26-Apr-2018* | 8 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 female mixed breeds cats, 4 kg each one approximately (age unknown), were treated with FRONTLINE SPOT-ON CAT (FL) (lot and exp unknown), 1 vial per cat, topic, base of skull and btw the shoulder blades, 'last month' (1 Mar 2018 chosen at random), for flea prevention. Lack of efficacy suspected because she discovered fleas on her cats on date not specified. Dose frequency unknown and first dose on date not specified (1 Jul 2018 chosen at random), environmental factors unknown. Similar case reported on 18BR003258. No further information is available. |
| 26-Apr-2018 | UAE; 18BR003258; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT | 01-Jul-2017* | 26-Apr-2018* | 8 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, 1 male mixed breeds cat, 4 kg approximately (age unknown), was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (lot and |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 4 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | exp unknown), base of skull and btw the shoulder blades, 'last month' (1 Mar 2018 chosen at random), for flea prevention. Lack of efficacy suspected because she discovered fleas on her cat on date not specified. Dose frequency unknown and first dose on date not specified (1 Jul 2018 chosen at random), environmental factors unknown. Similar case reported on 18BR003257. No further information is available. |
| 25-Apr-2018 | UAE; 18BR003259; GO; Brazil | **Species:** Canine<br>**Breed:** Retriever (Golden)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 47.00 Day(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 24-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Jack, a 47-day-old, 4 kg, male, Golden Retriever, was treated with FRONTLINE SPRAY (FL) (014/16, exp unknown), by the reporter, yesterday (24 Apr 2018). Following product application, the pup started experiencing apathy. This is the extent of the information available. |
| 26-Apr-2018 | UAE; 18BR003260; SP; Brazil | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 9.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 26-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Belinha, 8 years old, 9.7 kilogram, canine, female, Poodle, received FRONTLINE SPOT-ON DOGS S (FL) (lot 004/17 and exp date unknown, topically, between the shoulder blades ), applied by the reporter on 23 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her dog. The environment has been treated with BUTOX®. Belinha does not have contact with other dogs. The owner already used FRONTLINE SPRAY® in the past without issues. No further information is available. |
| 26-Apr-2018 | UAE; 18BR003262; MG; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Month(s)<br>**Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 19-Apr-2018* | 26-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Pandora, 9 months old, 4.5 kilogram, canine, female, Mixed Breed, received FRONTLINE SPRAY 100 mL (FL) (lot 003/17 and exp date unknown, topically, in the whole body for several times ), applied by the reporter on 26 Apr 2018 and for the first time 1 week ago (19 Apr 2018 – estimated date), for tick treatment. The owner complained about the lack of efficacy because he continues to see ticks in his dog. According to the owner, animal already had ticks 15 days prior to treament. The environment has been treated with BUTOX®. There is also another dog in the same household with a similar problem (see case 18BR003263). The dog does not go to the streets anymore. No further information is available. |
| 26-Apr-2018 | UAE; 18BR003263; MG; Brazil | **Species:** Canine<br>**Breed:** Pug<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Month(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 19-Apr-2018* | 26-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Jack, 6 years old, 6 kilogram, canine, male, Pug, received FRONTLINE SPRAY 100 mL (FL) (lot 003/17 and exp date unknown, topically, in the whole body for several times), applied by the reporter on 26 Apr 2018 and for the first time 1 week ago (19 Apr 2018 – estimated date), for tick treatment. The owner complained about the lack of efficacy because he continues to see ticks in his dog . According to the owner, animal already had ticks 15 days prior to treament. The environment has been treated with BUTOX®. There is also another dog in the same household with a similar problem (see case 18BR003262). The dog does not go to the streets anymore. No further information is available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 26-Apr-2018 | UAE; 18BR003266; SP; Brazil | **Species:** Canine **Breed:** Chowchow **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 05-Apr-2018 | 13-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Kiara, a 7-year-old, 35 kg, female, Chow Chow, was treated with one vial of FRONTLINE PLUS DOG L (FL) (024/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 5 Apr 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Since FL was not working, another vial of FL was applied on 12 Apr 2018, however Kiara is still infested by ticks. Tick infestation one month prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 19-Apr-2018 | UAE; 18BR003269; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 26-Feb-2018* | 26-Feb-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, Kiara, a female Yorkshire of 3 years old and 2 kg, received, for the first time, FRONTLINE 'pipette' (unsubstantiated) (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 2 months ago (26 Feb 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet had fleas and she was itching (due to fleas). The environment has not been treated. NEXGARD was given and the pet is currently free of fleas. A similar case was reported on 18BR003167. There is also a cat in this household treated with a flea collar. No further information is expected. |
| 26-Apr-2018 | UAE; 18BR003271; SP; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 30 kg | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 26-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Rimen, a male large crossbred dog of 3 years old and 30 kg, received one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 19 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided 1 Jan 2017 - chosen at random). Similar cases were reported on 18BR003272 and 18BR003273. There are 6 more dogs in this household that were not treated with FL, but it is unknown if they were treated with another product against ectoparasites. No further information is expected. |
| 26-Apr-2018 | UAE; 18BR003272; SP; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 30 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 26-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Branco, a male large crossbred dog of 6 years old and 30 kg, received one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 19 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided 1 Jan 2017 - chosen at random). Similar cases were reported on 18BR003271 and 18BR003273. There are 6 more dogs in this household that were not treated with FL, but it is unknown if they were treated with another product against ectoparasites. No further information is expected.. No further information is expected. |
| 26-Apr-2018 | UAE; 18BR003273; | **Species:** Canine | 1 | 1 | 0 | **Product used:** FIPRONIL | 01-Jan-2017* | 26-Apr-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Quiara, a female large crossbred dog of 3 years old and 20 kg, |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | SP; Brazil | **Breed:** Large crossbred (>20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 20 kg | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | received one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 19 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided 1 Jan 2017 - chosen at random). Similar cases were reported on 18BR003271 and 18BR003272. There are 6 more dogs in this household that were not treated with FL, but it is unknown if they were treated with another product against ectoparasites. No further information is expected. |
| 26-Apr-2018 | UAE; 18BR003274; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 18.00 Month(s)<br>**Weight:** 2.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 26-Apr-2018* | 3 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Duda, a female Yorkshire of 18 months old and 2.6 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 3 weeks ago (5 Apr 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. No further information is expected. |
| 26-Apr-2018 | UAE; 18BR003276; SC; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 2.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 25-Apr-2018 | 25-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Frito, a male mixed breed cat of 2 years old and 5 kg, received, for the first time, one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 25 Apr 2018, at 8 pm, for flea/tick control. The pet was in good health prior to FL and has no history of adverse reactions. Some hours after product application, the pet presented with dilated pupil, increased salivation and loss of appetite. Another cat of this household also reacted after FL (See case 18BR003277). The owner suspects that the animal licked the product. The owner called to the vet, who recommended water ingestion to her pet. It is unknown if the pet recovered. No further information is available. |
| 26-Apr-2018 | UAE; 18BR003277; SC; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 25-Apr-2018 | 25-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Amora, a female mixed breed cat of 5 years old and 3 kg, received, for the first time, one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 25 Apr 208, at 8 pm, for flea/tick control. The pet was in good health prior to FL and has no history of adverse reactions. Some hours after product application, the pet presented with dilated pupil, increased salivation and loss of appetite. Another cat of this household also reacted after FL (See case 18BR003276). The owner suspects that the animal licked the product. The owner called to the vet, who recommended water ingestion to her pet. It is unknown if the pet recovered. No further information is available. |
| 27-Apr-2018 | UAE; 18BR003280; SC; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / | 01-Jan-2017* | 27-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Mileide, a female small crossbred dog of 13 years old and 8 kg, received one vial of FRONTLINE SPOT ON DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades, overdose), applied by the reporter on 24 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Age:** 13.00 Year(s)<br>**Weight:** 8 kg | | | | Cutaneous<br>**Was the product used ok?:** No (Overdose) | | | | | product. FL has been applied monthly (first application was not provided - 1 Jan 2017 chosen at random). No further information is expected. |
| 27-Apr-2018 | UAE; 18BR003281; MG; Brazil | **Species:** Canine<br>**Breed:** Maltese<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 27-Apr-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Melissa, a female Maltese of 1 year old and 2 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 15 days ago (12 Apr 2018 - estimated date), for tick treatment. Lack of efficacy is suspected because the pet remains with ticks . The dog does not has outdoor access. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 27-Apr-2018 | UAE; 18BR003289; SP; Brazil | **Species:** Canine<br>**Breed:** West Highland White<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 8.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Overdose) | N/A | 27-Apr-2018* | 20 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Flor, 5 years old, 8.7 kilogram, canine, female, West Highland Terrier, received 1 and a half pipette of FRONTLINE PLUS DOG S (FL) (lot 018/17 and exp date unknown, topically, between the shoulder blades), applied by the reporter on 7 Apr 2018, for tick treatment. The owner complained about the lack of efficacy because the ticks were killed but after some weeks fleas appeared in her dog. The environment has been treated with BUTOX®. The owner saw a tick on her wall. There is also another dog in the same household with similar problem (see case 18BR003290). The dog does not have contact with other dogs on the street. The neighbor has a dog. No further information is available. |
| 27-Apr-2018 | UAE; 18BR003290; SP; Brazil | **Species:** Canine<br>**Breed:** West Highland White<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 27-Apr-2018* | 20 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Flai, 2 years old, 9 kilogram, canine, female, West Highland Terrier, received 1 and a half pipette of FRONTLINE PLUS DOG S (FL) (lot 018/17 and exp date unknown, topically, between the shoulder blades), applied by the reporter on 7 Apr 2018, for tick treatment. The owner complained about the lack of efficacy because the ticks were killed but after some weeks fleas appeared in her dog. The environment has been treated with BUTOX®. The owner saw a tick on her wall. There is also another dog in the same household with similar problem (see case 18BR003289). The dog does not have contact with other dogs on the street. The neighbor has a dog. No further information is available. |
| 27-Apr-2018 | UAE; 18BR003294; RS; Brazil | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 15-Mar-2017* | 27-Apr-2018* | 6 Week(s) 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Shakira, 3 years old, 3 kilogram, feline, female, Siamese, received 1 dose of FRONTLINE PLUS CATS (FL)(lot 007/17 and exp date unknown, topically , between the shoulder blades), applied by the owner in the middle of February (14 Feb 2018 – estimated date) and in the middle of march (15 Mar 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. The environment has been treated by a company. According to the owner her complaints are only for those 2 applications (first date 15 mar 2017 – date chosen at random). There is no further information available. |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **ok?:** Yes | | | | | |
| 27-Apr-2018 | UAE; 18BR003298; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 1.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 25-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 3 Yorkies of unknown signalment were treated with FRONTLINE (unsubstantiated) (lot and exp unknown), by the reporter, on date not specified (1 Apr 2018 chosen at random). Lack of efficacy suspected because the dogs were scratching and the owner discovered fleas on them on date not specified. This is the extent of the information available. UPDATE 2 MAY 2018 - The owner was contacted and reported that Bela, a female Yorkshire of 3 years old and 1.7 kg, was treated with FL PLUS DOG S (FL) (018/17 and unknown exp date, topical, between the shoulder blades), applied by the reporter last week (25 Apr 2018 - estimated date), for flea treatment. The pet remains with fleas. The environment has not been treated and FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR003366 and 18BR003367. No further information is expected. |
| 30-Apr-2018 | UAE; 18BR003299; PB; Brazil | **Species:** Canine **Breed:** Schnauzer **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 8.3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 08-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Duck, a 4-year-old, 8.3 kg, male, Schnauzer, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 7 Apr 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation one week prior to FL, outdoor access, environment not treated. FRONTLINE was applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2017 chosen at random). No further information is available. |
| 30-Apr-2018 | UAE; 18BR003300; RJ; Brazil | **Species:** Canine **Breed:** Rottweiler **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 23-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Haila, 3 years old, 35 kilogram, canine, female, Rottweiler, received 1 dose of FRONTLINE SPOT-ON DOGS L (FL) (lot 010/17 and exp date unknown, topically, between the shoulder blades ), applied by the owner on 23 Apr 2018, for flea treatment. The owner complained about the lack of efficacy, because her pet continued scratching. The environment has been treated with TALFON®. According to the owner her animal already had fleas for 3 days prior to treatment. The owner said that her dogs got fleas from her neighbor´s dog. There are another 2 dogs in the same household with similar problem (see cases 18BR003301 and 18BR003302). Only 1 flea was found in one of the animals, the owner did not identify which one. There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003301; RJ; Brazil | **Species:** Canine **Breed:** Rottweiler **Sex:** M **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 38.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 23-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Hulk, 18 months old, 38.5 kilogram, canine, male, Rottweiler, received 1 dose of FRONTLINE SPOT-ON DOGS L (FL) (lot 010/17 and exp date unknown, topically, between the shoulder blades ), applied by the owner on 23 Apr 2018, for flea treatment. The owner complained about the lack of efficacy, because her pet continued scratching. The environment has been treated with TALFON®. According to the owner her animal already had fleas for 3 days prior to treatment. The owner said that her dogs got fleas from her neighbor´s dog. There are another 2 dogs in the same household with similar problem (see cases 18BR003300 and 18BR003302). Only 1 flea was found in one of the animals, the owner did not identify which one. There is no further information available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 30-Apr-2018 | UAE; 18BR003302; RJ; Brazil | **Species:** Canine **Breed:** Rottweiler **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 23-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Akira, 3 years old, 37 kilogram, canine, female, Rottweiler, received 1 dose of FRONTLINE SPOT-ON DOGS L (FL) (lot 010/17 and exp date unknown, topically, between the shoulder blades ), applied by the owner on 23 Apr 2018, for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. The environment has been treated with TALFON®. According to the owner her animal already had fleas for 3 days prior to treatment. The owner said that her dogs got fleas from her neighbor´s dog. There are another 2 dogs in the same household with similar problem (see cases 18BR003300 and 18BR003301). Only 1 flea was found in one of the animals, the owner did not identify which one. There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003306; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 30-Apr-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Belinha, 3 months old, 2 kilogram, canine, female, Shih Tzu, received 1 dose of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date unknown, topically, from the back of the neck to the back of the animal), applied by the owner on 15 Apr 2018, for tick treatment. The owner complained about the lack of efficacy, because her pet continued with ticks, was taken to a veterinary before yesterday (28 Apr 2018 - estimated date) and was diagnosed with tick borne disease and is much weakened. The environment has not been treated. According to the owner, her animal already came with ticks since she was born. The owner also complained about the lack of efficacy of FRONTLINE SPRAY® (see case 18BR003307). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003307; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Yes | N/A | 30-Apr-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Belinha, 3 months old, 2 kilogram, canine, female, Shih Tzu, received, FRONTLINE SPRAY (FL) (lot, exp date, route and site of administration unknown), applied by an unidentified person on Saturday (28 Apr 2018 – estimated date), for tick treatment. The owner complained about the lack of efficacy, because her pet continued with ticks, was taken to a veterinary before yesterday (28 Apr 2018 - estimated date) and was diagnosed with tick borne disease and is much weakened. The environment has not been treated. According to the owner, her animal already came with ticks since she was born. The owner also complained about the lack of efficacy of FRONTLINE SPOT-ON DOGS S® (see case 18BR003306). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003308; PR; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** M **Sex qualifier:** Unknown **Age:** 19.00 Month(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 30-Apr-2018* | 7 Week(s) 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Thor, 19 months old, 7 kilogram, canine, male, Lhasa Apso, received, FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner on the first week of March (7 Mar 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, animal already had fleas 1 day prior to treatment. The environment has been treated with household products. As FL did not work 1 pipette of FRONTLINE PLUS DOG S was applied 13 days post FL. It is unknown if FRONTLINE was previously used. The actual health state of the dog is unknown. There is no further information available. |
| 27-Apr-2018 | UAE; 18BR003315; | **Species:** Canine **Breed:** | 1 | 1 | 0 | **Product used:** FIPRONIL | 20-Feb-2017* | 30-Apr-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, an unidentified numbers of dogs, FRONTLINE SPRAY 250 mL (FL) |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | BA; Brazil | Pomeranian<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 3.2 kg | | | | SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | (lot, exp date, route and site of administration unknown), applied by the owner on an unidentified date (15 Apr 2018 – Date chosen at random), for flea treatment. The owner complained about the lack of efficacy, because her pets continued with fleas . According to the owner she already used FL in the past with no issues (20 Feb 2017 – date chosen at random). There is no further information available. UPDATE 3 MAY 2018 - Pancho, 4 years old, 3.2 kilogram, canine, male, Pomeranian, received FL (lot 015/16, exp date unknown, topically, in the whole body ), applied by the owner on 24 Apr 2018 for flea and tick treatment. the owner complained about the lack of efficacy because her dog remains with both parasites. According to the owner, animal already had parasites 15 to 20 days prior to treatment. The owner already used FL in the past in 5 adult dogs and had results. 2 days prior to treatment, the environment floor has been treated with BUTOX®, the walls and ceilings were swept. The animal goes for a walk on the street every 20 days. There are another 7 dogs in the same household with a similar problem (see cases 18BR003377 to 18BR003383). No further information is available. |
| 27-Apr-2018 | UAE; 18BR003317; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 13.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 01-Apr-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Sofie, a female Yorkshire of 13 years old and 3 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 29 Mar 2018, for flea treatment. Lack of efficacy is suspected because the pet continued infested by fleas. In addition, the pet has flea allergic dermatitis. The environment has been treated with an unknown product. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). 15 days ago (18 Apr 2018), Neopet® was applied on Sofie and she is free of fleas. A similar case was reported on 18BR003317. No further information is expected. |
| 30-Apr-2018 | UAE; 18BR003324; RJ; Brazil | **Species:** Canine<br>**Breed:** Pug<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Month(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 28-Feb-2018* | 28-Feb-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Panco, a 4-month-old, 5 kg, male, Pug, has been treated with FRONTLINE SPRAY (FL) (013/16, Nov 2018), topic, whole body, by the reporter, since 2 months ago (presumed 28 Feb 2018), last dose today (30 Apr 2018), for flea treatment. Same bottle was applied several times to the dog. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation prior to FL, environment treated with K-Othrine. No further information is available. |
| 30-Apr-2018 | UAE; 18BR003325; PR; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products | N/A | 30-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Anitta, a female mixed breed cat of 5 months old and 2 kg, received one vial of FRONTLINE PLUS CATS (FL) (001/17 and unknown exp date, topical, btw the shoulder blades), applied by the reporter on 29 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. No further information is expected. UPDATE 17 MAY 2018 - According to the owner, the pet remains with fleas. No |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Month(s)<br>**Weight:** 2 kg | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | further information is available. |
| 30-Apr-2018 | UAE; 18BR003326; BA; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 13.00 Year(s)<br>**Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 22-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Leeloo, a 13-year-old, 9 kg, female, Shih Tzu, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, between the shoulder blades, by the reporter, on 21 Apr 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 5 days prior to FL, environment not treated. 2 other dogs of the same household that are also on FL were reported on 18BR003327 and 18BR003328. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 30-Apr-2018 | UAE; 18BR003327; BA; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 22-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pietro, an 8-year-old, 5 kg, male, Shih Tzu, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, between the shoulder blades, by the reporter, on 21 Apr 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 5 days prior to FL, environment not treated. 2 other dogs of the same household that are also on FL were reported on 18BR003326 and 18BR003328. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 30-Apr-2018 | UAE; 18BR003328; BA; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 22-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Tchuby, a 3-year-old, 8 kg, male, Shih Tzu, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, between the shoulder blades, by the reporter, on 21 Apr 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 5 days prior to FL, environment not treated. 2 other dogs of the same household that are also on FL were reported on 18BR003326 and 18BR003327. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 30-Apr-2018 | UAE; 18BR003329; RJ; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 8 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 30-Mar-2018* | 30-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sophia, a female Lhasa Apso of 4 years old and 8 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (017/16 and unknown exp date, topical, whole body), applied by the reporter today (30 Apr 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and FL was applied for the first time one month ago with the same issue (30 Mar 2018 - estimated date). There is a cat in this household with the same issue (see case 18BR003330). The owner also complained about the lack of efficacy of FRONTLINE PLUS DOG S (See case |

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| | | | | | | | | | | | 18BR003331) and FRONTLINE PLUS CATS (See case 18BR003332). No further information is expected. |
| 30-Apr-2018 | UAE; 18BR003330; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 30-Mar-2018* | 30-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Preto, a male mixed breed cat of 1 year old and 1 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (017/16 and unknown exp date, topical, whole body), applied by the reporter today (30 Apr 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and FL was applied for the first time one month ago with the same issue (30 Mar 2018 - estimated date). There is a dog in this household with the same issue (see case 18BR003329). The owner also complained about the lack of efficacy of FRONTLINE PLUS DOG S (See case 18BR003331) and FRONTLINE PLUS CATS (See case 18BR003332). No further information is expected. |
| 30-Apr-2018 | UAE; 18BR003331; RJ; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 8 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sophia, a female Lhasa Apso of 4 years old and 8 kg, was treated with FRONTLINE PLUS DOG S (FL) (lot, exp date, route and location are unknown), applied by the reporter 45 days ago (15 Mar 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. There is a cat in this household with the same issue (see case 18BR003332). The owner also complained about the lack of efficacy of FRONTLINE SPRAY (See cases 18BR003329 and 18BR003330). No further information is expected. |
| 30-Apr-2018 | UAE; 18BR003332; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 8 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 30-Apr-2018* | 6 Week(s) 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Preto, a male mixed breed cat of 1 year old and 8 kg, was treated with FRONTLINE PLUS CATS (FL) (lot, exp date, route and location are unknown), applied by the reporter 45 days ago (15 Mar 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. There is a dog in this household with the same issue (see case 18BR0033331). The owner also complained about the lack of efficacy of FRONTLINE SPRAY (See cases 18BR003329 and 18BR003330). No further information is expected. |
| 29-Apr-2018 | UAE; 18BR003336; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Jul-2017* | 15-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via social media, 1 dog of unknown signalment was treated with one vial of FRONTLINE PLUS DOGS S (FL) (lot and exp unknown), by the reporter, on 14 Apr 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas . UPDATE 30 APR 2018 – Preto, a 15-year-old, 10 kg, male, crossbred dog, received FL topic, base of skull and btw the shoulder blades. Lack of efficacy suspected because the dog is still scratching. No fleas have been seen on him. Flea infestation prior to FL, environment treated with Butox. FRONTLINE was applied near Jul 2017 with no issues (20 Jul 2017 chosen at random). Other dog of the same household that is also on FRONTLINE was reported on 18BR003337. No further information is available. |

N/A signifies the information for this field is either not available or not applicable

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 29-Apr-2018 | UAE; 18BR003337; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 20 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Jul-2017* | 15-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via social media, 1 dog of unknown signalment was treated with one vial of FRONTLINE PLUS DOGS L (FL) (lot and exp unknown), by the reporter, on 14 Apr 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. UPDATE 30 APR 2018 – Branca, a 5-year-old, 20 kg, female, crossbred dog, received FL topic, base of skull and btw the shoulder blades. Flea infestation since Jul 2017, when FRONTLINE was applied and did not work also (see 17BR003325), flea allergy dermatitis. Environment treated with Butox. Other dog of the same household that is also on FRONTLINE was reported on 18BR003336. No further information is available. |
| 30-Apr-2018 | UAE; 18BR003340; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 17.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 30-Apr-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Sophia, 17 years old, 4 kilogram, feline, female, Mixed Breed, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner 15 days ago (15 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, animal already had fleas 2 weeks prior to treatment. The environment has been treated but the owner did not know to inform the product´s name. The owner also has another cat in the same household with a similar problem (see case 18BR003341). The owner also said that 2 years ago she used FRONTLINE® in her mother´s female dog and it didn´t work, according to her she used the FRONTLINE that also works in the environment (see case 18BR003342). It is unknown if FL was previously used by the cats. According to the owner, the cats do not have contact with other animals. There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003341; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 16.00 Year(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 30-Apr-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Branquinha, 16 years old, 2 kilogram, feline, female, Mixed Breed, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner 15 days ago (15 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, animal already had fleas 2 weeks prior to treatment. The environment has been treated but the owner did not know to inform the product´s name. The owner also has another cat in the same household with a similar problem (see case 18BR003340). The owner also said that 2 years ago she used FRONTLINE® in her mother´s female dog and it didn´t work, according to her she used the FRONTLINE that also works in the environment (see case 18BR003342). It is unknown if FL was previously used by the cats. According to the owner, the cats do not have contact with other animals. There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003342; RJ; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the** | N/A | 30-Apr-2016* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner´s daughter, an unidentified female dog, received FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by an unknown person 2 years ago (30 Apr 2016 – date chosen at random), for unknown reason. The owner´s daughter complained about the lack of efficacy, because FL did not work. The reporter has 2 cats living in a same household with a suspected lack of efficacy regarding FRONTLINE PLUS CATS (see cases |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **product used ok?:** Unknown to Company | | | | | 18BR003340 and 18BR003341). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003345; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Maria Fardinha, 14 years old, 4 kilogram, feline, female, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003346 to 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003346; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Fibi, 11 years old, 3 kilogram, feline, female, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345 and 18BR003347 to 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003347; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Corti, 10 years old, 6 kilogram, feline, male, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345, 18BR003346 and 18BR003348 to 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003348; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Morgana, 6 years old, 5 kilogram, feline, female, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 5 kg | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345 to 18BR003347 and 18BR003349 to 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003349; -; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Megui, 6 years old, 5 kilogram, feline, female, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345 to 18BR003348 and 18BR003350 to 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003350; -; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Moli, 6 years old, 6 kilogram, feline, female, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345 to 18BR003349 and 18BR003351 to 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003351; -; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Fiuke, 6 years old, 6 kilogram, feline, male, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345 to 18BR003350 and |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | 18BR003352 to 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003352; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Manuel, 6 years old, 6 kilogram, feline, male, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345 to 18BR003351 and 18BR003353 to 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003353; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Olivia, unknown age, 6 kilogram, feline, female, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345 to 18BR003352 and 18BR003354 to 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003354; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Raul, 2 years old, 6 kilogram, feline, male, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345 to 18BR003353 and 18BR003355 to 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003355; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Maria Clara, 5 years old, 4 kilogram, feline, female, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 4 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345 to 18BR003354, 18BR003356 and 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003356; -; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Tiquininha, 4 years old, 4 kilogram, feline, female, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345 to 18BR003355 and 18BR003357). There is no further information available. |
| 30-Apr-2018 | UAE; 18BR003357; -; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Jan-2018* | 21-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Maria Preta, unknown age, 5 kilogram, feline, female, Mixed Breed, received, FRONTLINE SPRAY 250 mL (FL) (lot 015/16 and exp date unknown, topically, in the whole body), applied by the owner on Thursday (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, FL was used as soon as she noticed her cat with fleas. The owner also used a different flask of FL on January and February (20 Jan and 20 Feb 2018 – date chosen at random) without results. The environment has been treated with K-OTHRINE®, an unidentified spray and alcohol. The cat´s bed has been cleaned too and she does not see fleas in the environment. There are another 12 cats in the same household with similar problem (see cases 18BR003345 to 18BR003356). There is no further information available. |
| 02-May-2018 | UAE; 18BR003362; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Month(s)<br>**Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 02-May-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Guilbert, 6 months old, 2.5 kilogram, feline, male, Mixed Breed, received, FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 26 Apr 2018, for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas. According to the owner, animal already had fleas 1 month prior to treatment. The owner also treated her pet with FRONTLINE SPRAY® 1 month ago without results (see case 18BR003363). The environment has been treated with K-OTHRINE®. It is unknown if the animal already used FL in the past. There is no further information available. |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 02-May-2018 | UAE; 18BR003363; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 02-May-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Guilbert, 6 months old, 2.5 kilogram, feline, male, Mixed Breed, received, FRONTLINE SPRAY (FL) (lot, exp date, route and site of administration unknown), applied by the owner 1 month ago (2 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with fleas . According to the owner, animal already had fleas 1 month prior to treatment. The owner also treated her pet with FRONTLINE PLUS CATS without results (see case 18BR003362). The environment has been treated with K-OTHRINE®. It is unknown if the animal already used FL in the past. There is no further information available. |
| 27-Apr-2018 | UAE; 18BR003366; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 3.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 27-Apr-2018* | 2 Day(s) | D-D | Lack of Efficacy Claim: As reported by the pet owner via social media, Alvin, a male Yorkshire of 5 years old and 3.8 kg, was treated with FL PLUS DOG S (FL) (018/17 and unknown exp date, topical, between the shoulder blades), applied by the reporter last week (25 Apr 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . In addition, the pet is scratching himself due to fleas. The environment has not been treated and FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR003298 and 18BR003367. No further information is expected. |
| 27-Apr-2018 | UAE; 18BR003367; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 27-Apr-2018* | 2 Day(s) | D-D | Lack of Efficacy Claim: As reported by the pet owner, Simon, a male Yorkshire of 5 years old and 5 kg, was treated with FL PLUS DOG S (FL) (018/17 and unknown exp, topical, between the shoulder blades), applied by the reporter last week (25 Apr 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, the pet is scratching herself due to fleas. The environment has not been treated and FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR003298 and 18BR003366. No further information is expected. |
| 30-Apr-2018 | UAE; 18BR003372; RJ; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 11-Apr-2018 | 30-Apr-2018* | 19 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, Airon, a male Shih Tzu of 7 years old and 4.5 kg, received, for the first time, one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, between the shoulder blades), applied by the reporter 3 weeks ago (11 Apr 2018), for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has not been treated. The dog has outdoor access. FRONTLINE SPRAY was applied in the past with no issue. No further information is expected. |
| 02-May-2018 | UAE; 18BR003373; SC; Brazil | **Species:** Canine **Breed:** Dalmatian **Sex:** F **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | N/A | 02-May-2018* | 11 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Kiara, a female Dalmatian of 1 year old and 46 kg, received one vial of FRONTLINE PLUS DOG XL (FL) (lot and exp date are unknown, topical, lumbar - off label), applied by the reporter on 21 |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 46 kg | | | | 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with a powder against fleas and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (see case 18BR003374). No further information is expected. |
| 02-May-2018 | UAE; 18BR003374; SC; Brazil | **Species:** Canine<br>**Breed:** Dalmatian<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 18.00 Month(s)<br>**Weight:** 36 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 02-May-2018* | 11 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Zeus, a male Dalmatian of 18 months old and 36 kg, received one vial of FRONTLINE PLUS DOG L (FL) (007/16 and unknown exp date, topical, lumbar - off label), applied by the reporter on 21 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with a powder against fleas and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (see case 18BR003373). No further information is expected. |
| 30-Apr-2018 | UAE; 18BR003375; -; Brazil | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 20-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 2 cats of unknown signalment were treated with FRONTLINE (unsubstantiated) (lot and exp unknown), by the reporter, on date not specified (20 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cats continued to have fleas. There is no further information available. |
| 27-Apr-2018 | UAE; 18BR003377; BA; Brazil | **Species:** Canine<br>**Breed:** Pomeranian<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Feb-2017* | 30-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Toy Story, 3 years old, 4 kilogram, canine, male, Pomeranian, received FRONTLINE SPRAY 250 mL (FL) (lot 015/16, exp date unknown, topically, in the whole body), applied by the owner on 24 Apr 2018 for flea and tick treatment. the owner complained about the lack of efficacy because her dog remains with both parasites. According to the owner, animal already had parasites 15 to 20 days prior to treatment. The owner already used FL in the past in 5 adult dogs and had results. 2 days prior to treatment, the environment floor has been treated with BUTOX®, the walls and ceilings were swept. The animal goes for a walk on the street every 20 days. There are another 7 dogs in the same household with a similar problem (see cases 18BR003315 and 18BR003378 to 18BR003383). The owner |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | already used FL in the past with no issues (20 Feb 2017 - date chosen at random). No further information is available. |
| 27-Apr-2018 | UAE; 18BR003378; BA; Brazil | **Species:** Canine **Breed:** Pomeranian **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Feb-2017* | 30-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Sorte, 3 years old, 4 kilogram, canine, female, Pomeranian, received FRONTLINE SPRAY 250 mL (FL) (lot 015/16, exp date unknown, topically, in the whole body), applied by the owner on 24 Apr 2018 for flea and tick treatment. the owner complained about the lack of efficacy because her dog remains with both parasites. According to the owner, animal already had parasites 15 to 20 days prior to treatment. The owner already used FL in the past in 5 adult dogs and had results. 2 days prior to treatment, the environment floor has been treated with BUTOX®, the walls and ceilings were swept. The animal goes for a walk on the street every 20 days. There are another 7 dogs in the same household with a similar problem (see cases 18BR003315, 18BR003377 and 18BR003379 to 18BR003383). The owner already used FL in the past with no issues (20 Feb 2017 - date chosen at random). No further information is available. |
| 27-Apr-2018 | UAE; 18BR003379; BA; Brazil | **Species:** Canine **Breed:** Pomeranian **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 2.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Feb-2017* | 30-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Allegra, 2 years old, 2.2 kilogram, canine, female, Pomeranian, received FRONTLINE SPRAY 250 mL (FL) (lot 015/16, exp date unknown, topically, in the whole body), applied by the owner on 24 Apr 2018 for flea and tick treatment. the owner complained about the lack of efficacy because her dog remains with both parasites. According to the owner, animal already had parasites 15 to 20 days prior to treatment. The owner already used FL in the past in 5 adult dogs and had results. 2 days prior to treatment, the environment floor has been treated with BUTOX®, the walls and ceilings were swept. The animal goes for a walk on the street every 20 days. There are another 7 dogs in the same household with a similar problem (see cases 18BR003315, 18BR003377, 18BR003378 and 18BR003380 to 18BR003383). The owner already used FL in the past with no issues (20 Feb 2017 - date chosen at random). No further information is available. |
| 27-Apr-2018 | UAE; 18BR003380; BA; Brazil | **Species:** Canine **Breed:** Pomeranian **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Feb-2017* | 30-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Violeta, 2 years old, 2 kilogram, canine, female, Pomeranian, received FRONTLINE SPRAY 250 mL (FL) (lot 015/16, exp date unknown, topically, in the whole body), applied by the owner on 24 Apr 2018 for flea and tick treatment. the owner complained about the lack of efficacy because her dog remains with both parasites. According to the owner, animal already had parasites 15 to 20 days prior to treatment. The owner already used FL in the past in 5 adult dogs and had results. 2 days prior to treatment, the environment floor has been treated with BUTOX®, the walls and ceilings were swept. The animal goes for a walk on the street every 20 days. There are another 7 dogs in the same household with a similar problem (see cases 18BR003315, 18BR003377 to 18BR003379 and 18BR003381 to 18BR003383). The owner already used FL in the past with no issues (20 Feb 2017 - date chosen at random). No further information is available. |
| 27-Apr-2018 | UAE; 18BR003381; BA; Brazil | **Species:** Canine **Breed:** Pomeranian **Sex:** F **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other | 20-Feb-2017* | 30-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Amora, 7 months old, 1.7 kilogram, canine, female, Pomeranian, received FRONTLINE SPRAY 250 mL (FL) (lot 015/16, exp date unknown, topically, in the whole body), applied by the owner on 24 Apr 2018 for flea and tick treatment. the owner complained about |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Unknown<br>**Age:** 7.00 Month(s)<br>**Weight:** 1.7 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | the lack of efficacy because her dog remains with both parasites. According to the owner, animal already had parasites 15 to 20 days prior to treatment. The owner already used FL in the past in 5 adult dogs and had results. 2 days prior to treatment, the environment floor has been treated with BUTOX®, the walls and ceilings were swept. The animal goes for a walk on the street every 20 days. There are another 7 dogs in the same household with a similar problem (see cases 18BR003315, 18BR003377 to 18BR003380, 18BR003382 and 18BR003383). The owner already used FL in the past with no issues (20 Feb 2017 - date chosen at random). No further information is available. |
| 27-Apr-2018 | UAE; 18BR003382; BA; Brazil | **Species:** Canine<br>**Breed:** Pomeranian<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Month(s)<br>**Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Feb-2017* | 30-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Hanna, 7 months old, 1.5 kilogram, canine, female, Pomeranian, received FRONTLINE SPRAY 250 mL (FL) (lot 015/16, exp date unknown, topically, in the whole body), applied by the owner on 24 Apr 2018 for flea and tick treatment. the owner complained about the lack of efficacy because her dog remains with both parasites. According to the owner, animal already had parasites 15 to 20 days prior to treatment. The owner already used FL in the past in 5 adult dogs and had results. 2 days prior to treatment, the environment floor has been treated with BUTOX®, the walls and ceilings were swept. The animal goes for a walk on the street every 20 days. There are another 7 dogs in the same household with a similar problem (see cases 18BR003315, 18BR003377 to 18BR003381 and 18BR003383). The owner already used FL in the past with no issues (20 Feb 2017 - date chosen at random). No further information is available. |
| 27-Apr-2018 | UAE; 18BR003383; BA; Brazil | **Species:** Canine<br>**Breed:** Pomeranian<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Month(s)<br>**Weight:** 1.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Feb-2017* | 30-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Laila, 7 months old, 1.7 kilogram, canine, female, Pomeranian, received FRONTLINE SPRAY 250 mL (FL) (lot 015/16, exp date unknown, topically, in the whole body), applied by the owner on 24 Apr 2018 for flea and tick treatment. the owner complained about the lack of efficacy because her dog remains with both parasites. According to the owner, animal already had parasites 15 to 20 days prior to treatment. The owner already used FL in the past in 5 adult dogs and had results. 2 days prior to treatment, the environment floor has been treated with BUTOX®, the walls and ceilings were swept. The animal goes for a walk on the street every 20 days. There are another 7 dogs in the same household with a similar problem (see cases 18BR003315, 18BR003377 to 18BR003382). The owner already used FL in the past with no issues (20 Feb 2017 - date chosen at random). No further information is available. |
| 03-May-2018 | UAE; 18BR003385; SP; Brazil | **Species:** Canine<br>**Breed:** Schnauzer<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 30-Apr-2018 | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bidu, a male Schnauzer of 2 years old and 9 kg, received one vial of FRONTLINE PLUS DOG S (FL) (023/17 and unknown exp date, topical, between the shoulder blades), applied by the reporter on 25 Apr 2018, for tick control. Lack of efficacy is suspected because ticks were found on her pet on 30 Apr 2018. The environment has not been treated and it is unknown if FL has previously been applied. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 01-May-2018 | UAE; 18BR003386; RS; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 15-Jan-2018* | 01-May-2018* | 16 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, an unidentified canine, male, received FRONTLINE SPRAY 250 mL (FL) (lot, exp date, route and site of administration unknown), applied by the owner on an unspecified date (15 Apr 2018 – date chosen at random) for flea treatment. The owner complained about the lack of efficacy because FL works for 2 days but then her dog got fleas again. According to the owner, she has used FL for 2 or 3 months without results (15 Jan 2018 – date chosen at random). No further information is available. |
| 03-May-2018 | UAE; 18BR003387; SP; Brazil | **Species:** Canine **Breed:** Bull Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 17 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 03-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pandora, a female Bull Terrier of 4 years old and 17 kg, received one vial of FRONTLINE SPOT-ON DOG M (FL) (lot and exp date are unknown, topical, neck - incorrect application), applied by the reporter on 26 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and FL is applied every 20 to 25 days (first application was not provided - 1 Jan 2017 chosen at random). No further information is expected. |
| 03-May-2018 | UAE; 18BR003392; SP; Brazil | **Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 03-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the owner, Princy, 10 years old, 8 kilogram, canine, female, Pinscher, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner 1 week ago (26 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy, because her pet continued with live fleas. According to the owner, animal already had fleas 2 days prior to treatment. The environment has not been treated. The owner takes the dog to walk on the street 3 to 4 times a week. It is unknown if the owner already gave FL to her dog in the past. There is no further information available. |
| 03-May-2018 | UAE; 18BR003396; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.50 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 02-May-2018 | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Charlote, a female small crossbred dog of 3.5 years old and 4 kg, received one vial of FRONTLINE SPOT-ON CAT (FL) (lot and exp date are unknown, topical, between the shoulder blades), applied by the reporter on 29 Apr 2018, for flea control. The owner believes that FL is not working because she found 1 flea on her pet on 2 May 2018. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. There are 3 more cats in this household that were treated with FL and they have no issue. No further information is expected. |
| 03-May-2018 | UAE; 18BR003398; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | N/A | 22-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Toddyinho, a male medium crossbred dog of 6 years old and 18 kg, received one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown), applied by the reporter on 22 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 18 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | remains with fleas since the application of the product. The environment has not been treated and it is unknown if FL has previously been applied. No further information is expected. |
| 27-Apr-2018 | UAE; 18BR003406; RJ; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.50 Year(s)<br>**Weight:** 7.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 27-Apr-2018* | 9 Week(s) 4 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Meg, a female Shih Tzu of 2.5 years old and 7.5 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, from the base of skull to near the tail), applied by the reporter around 19 Feb 2018, for flea and tick treatment. Around 27 Apr 2018, the dog experienced hair loss and skin lesion. The symptoms are still ongoing. No vet care was provided. Similar cases were reported on 18BR003407 to 18BR003413. SLOE cases reported on 18BR002117 to 18BR002124. No further information is available. |
| 27-Apr-2018 | UAE; 18BR003407; RJ; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Month(s)<br>**Weight:** 2.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 27-Apr-2018* | 9 Week(s) 4 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Princesa, a female Shih Tzu of 12 months old and 2.8 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, from the base of skull to near the tail), applied by the reporter around 19 Feb 2018, for flea and tick treatment. Around 27 Apr 2018, the dog experienced hair loss and skin lesion. The symptoms are still ongoing. No vet care was provided. Similar cases reported on 18BR003406, 18BR003408 to 18BR003413. SLOE cases were reported on 18BR002117 to 18BR002124. No further information is available. |
| 27-Apr-2018 | UAE; 18BR003408; RJ; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Month(s)<br>**Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 19-Feb-2018* | 27-Apr-2018* | 9 Week(s) 4 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Billy, a male Shih Tzu of 1 month old and 1.5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (001/17 and unknown exp date, topical, parts of the body), applied by the reporter around 19 Feb 2018, for flea and tick treatment. Around 27 Apr 2018, the dog experienced hair loss and skin lesion. The symptoms are still ongoing. No vet care was provided. Similar cases reported on 18BR003406, 18BR003407, 18BR003409 to 18BR003413. SLOE cases reported on 18BR002117 to 18BR002124. No further information is available. |
| 27-Apr-2018 | UAE; 18BR003409; | **Species:** Canine<br>**Breed:** Shih Tzu | 1 | 1 | 0 | **Product used:** FIPRONIL | 19-Feb-2018* | 27-Apr-2018* | 9 Week(s) 4 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Floquinho, a male Shih Tzu of 1 month old and 1.5 kg, was |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | RJ; Brazil | **Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Month(s)<br>**Weight:** 1.5 kg | | | | SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | treated, for the first time, with FRONTLINE SPRAY (FL) (001/17 and unknown exp date, topical, parts of the body), applied by the reporter around 19 Feb 2018, for flea and tick treatment. Around 27 Apr 2018, the dog experienced hair loss and skin lesion. The symptoms are still ongoing. No vet care was provided. Similar cases reported on 18BR003406 to 18BR003408, 18BR003410 to 18BR003413. SLOE cases reported on 18BR002117 to 18BR002124. No further information is available. |
| 27-Apr-2018 | UAE; 18BR003410; RJ; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Month(s)<br>**Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 19-Feb-2018* | 27-Apr-2018* | 9 Week(s) 4 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Joy, a male Shih Tzu of 1 month old and 1.5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (001/17 and unknown exp date, topical, parts of the body), applied by the reporter around 19 Feb 2018, for flea and tick treatment. Around 27 Apr 2018, the dog experienced hair loss and skin lesion. The symptoms are still ongoing. No vet care was provided. Similar cases reported on 18BR003406 to 18BR003409, 18BR003411 to 18BR003413. SLOE cases reported on 18BR002117 to 18BR002124. No further information is available. |
| 27-Apr-2018 | UAE; 18BR003411; RJ; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Month(s)<br>**Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 19-Feb-2018* | 27-Apr-2018* | 9 Week(s) 4 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Meg Maria, a female Shih Tzu of 1 month old and 1.5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (001/17 and unknown exp date, topical, parts of the body), applied by the reporter around 9 Feb 2018, for flea and tick treatment. Around 27 Apr 2018, the dog experienced hair loss and skin lesion. The symptoms are still ongoing. No vet care was provided. Similar cases reported on 18BR003406 to 18BR003410, 18BR003412 and 18BR003413. SLOE cases reported on 18BR002117 to 18BR002124. No further information is available. |
| 27-Apr-2018 | UAE; 18BR003412; RJ; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Month(s)<br>**Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination | 19-Feb-2018* | 27-Apr-2018* | 9 Week(s) 4 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Joyce, a female Shih Tzu of 1 month old and 1.5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (001/17 and unknown exp date, topical, parts of the body), applied by the reporter around 9 Feb 2018, for flea and tick treatment. Around 27 Apr 2018, the dog experienced hair loss and skin lesion. The symptoms are still ongoing. No vet care was provided. Similar cases reported on 18BR003406 to 18BR003411 and 18BR003413. SLOE cases reported on 18BR002117 to 18BR002124. No further information is available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | program not respected) | | | | | |
| 27-Apr-2018 | UAE; 18BR003413; RJ; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Month(s) **Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 19-Feb-2018* | 27-Apr-2018* | 9 Week(s) 4 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Pamela, a female Shih Tzu of 1 month old and 1.5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (001/17 and unknown exp date, topical, parts of the body), applied by the reporter around 9 Feb 2018, for flea and tick treatment. Around 27 Apr 2018, the dog experienced hair loss and skin lesion. The symptoms are still ongoing. No vet care was provided. Similar cases reported on 18BR003406 to 18BR003412. SLOE cases reported on 18BR002117 to 18BR002124. No further information is available. |
| 27-Apr-2018 | UAE; 18BR003415; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 01-Apr-2018 | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Nani, a female Yorkshire of 14 years old and 4 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 29 Mar 2018, for flea treatment. Lack of efficacy is suspected because the pet continued infested by fleas. In addition, the pet has flea allergic dermatitis. The environment has been treated with an unknown product. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). 15 days ago (18 Apr 2018), Neopet® was applied on Nani and she is free of fleas. A similar case was reported on 18BR003317. No further information is expected. |
| 03-May-2018 | UAE; 18BR003416; PR; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 02-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lili, a 3-year-old, 2.5 kg, female, Shih Tzu, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, location unknown, by the reporter, on early Apr 2018 (1 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas . Flea infestation prior to FL, environment not treated, outdoor access. It is unknown if FRONTLINE was applied to the dog in the past. 1 other dog of the same household that is also on FL was reported on 18BR003417. There are other dogs in the household that received another company's product (details not provided). No further information is available. |
| 03-May-2018 | UAE; 18BR003417; PR; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 02-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mole, a 6-year, 5 kg, female, Poodle, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, location unknown, by the reporter, on early Apr 2018 (1 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation prior to FL, environment not treated, outdoor access. It is unknown if FRONTLINE was applied to the dog in the past. 1 other dog of the same household that is also on FL was reported on 18BR003416. There are other dogs in the household that received another company's product (details not provided). No further information is available. |

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| 03-May-2018 | UAE; 18BR003418; PR; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 13 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 22-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lupita, a 5-year-old, 13 kg, female, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 21 Apr 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 2 days prior to FL, environment treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 03-May-2018 | UAE; 18BR003419; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 19-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Esmeralda, a 6-month-old, female mixed breeds cat (weight unknown), was treated with one vial of FRONTLINE PLUS CATS (FL) (007/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 18 Apr 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 1 month prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the cat in the past. No further information is available. |
| 03-May-2018 | UAE; 18BR003420; SP; Brazil | **Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Meg, a 6-year-old, 5 kg, female, Siamese cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 16 Apr 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 15 days prior to FL, environment treated with My Pet. It is unknown if FRONTLINE was applied to the cat in the past. One other cat of the same household that is also on FL was reported on 18BR003421. No further information is available. |
| 03-May-2018 | UAE; 18BR003421; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bady, a 18-month-old, 3 kg, male, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 16 Apr 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 15 days prior to FL, environment treated with My Pet. It is unknown if FRONTLINE was applied to the cat in the past. One other cat of the same household that is also on FL was reported on 18BR003420. No further information is available. |
| 01-May-2018 | UAE; 18BR003422; | **Species:** Canine | 1 | 1 | 0 | **Product used:** FIPRONIL | 01-Jan-2017* | 29-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via social media, 2 female dogs were treated with |

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| | SP; Brazil | **Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Year(s)<br>**Weight:** 13 kg | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | FRONTLINE, by the reporter, 3 days ago (28 Apr 2018), for tick treatment. Lack of efficacy suspected because both dogs continued to have live attached ticks. UPDATE 3 MAY 2018 – The owner was contacted and she reported that Belinha, a 9-year-old, 13 kg, female, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, between the shoulder blades. Tick infestation prior to FL, environment not treated. FRONTLINE was applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2017 chosen at random). The other dog was reported on 18BR003423. No further information is available. |
| 01-May-2018 | UAE; 18BR003423; SP; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Year(s)<br>**Weight:** 13 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 29-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via social media, 2 female dogs were treated with FRONTLINE, by the reporter, 3 days ago (28 Apr 2018), for tick treatment. Lack of efficacy suspected because both dogs continued to have live attached ticks. UPDATE 3 MAY 2018 – The owner was contacted and she reported that Lilu, a 9-year-old, 13 kg, female, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, between the shoulder blades. Tick infestation prior to FL, environment not treated. FRONTLINE was applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2017 chosen at random). The other dog was reported on 18BR003422. No further information is available. |
| 03-May-2018 | UAE; 18BR003424; SP; Brazil | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 16.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2018* | 03-May-2018* | 8 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Maike, 16 years old, 5 kilogram, canine, male, Poodle, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 30 days ago (2 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because he continues to see fleas in his dog. According to the owner, the animal already had fleas 2 days prior to treatment. . The environment has not been treated. The owner already used FL in the past with no issues (01 Jan 2018 – date chosen at random). No further information is available. |
| 02-May-2018 | UAE; 18BR003425; SP; Brazil | **Species:** Canine<br>**Breed:** Akita<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 11-Apr-2016* | 02-May-2018* | 3 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Dexter, 5 years old, 35 kilogram, canine, male, Akita, received 1 pipette of FRONTLINE SPOT-ON DOGS XL (FL) (lot 008/17 and exp date DEC 2018, topically, between the shoulder blades), applied by the reporter on 11 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her dog. According to the owner, the animal already had fleas 2 days prior to treatment. The environment has been treated but the owner does not know the product´s name. The dog goes out dally for night walks and the owner believes that Dexter is getting fleas from the outside environment. The owner already used FL in the past with no issues (11 Apr 2016 – date chosen at random). No further information is available. UPDATE 7 MAY 2018 – FRONTLINE has been applied monthly with no issues. The owner believes that FL did not work as well as it used to because she did not find dead fleas on Dexter, only live ones. The dog is allergic to flea bite. There is no further information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 03-May-2018 | UAE; 18BR003428; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-May-2016* | 03-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Bruce, 5 years old, 3 kilogram, canine, male, Yorkshire, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot 018/17 and exp date unknown, topically, between the shoulder blades), applied by the reporter on 1 May 2018, for flea treatment. The owner complained about the lack of efficacy because he continues to see fleas in his dog. According to the owner, the animal already had fleas 2 days prior to treatment. The owner said that now his dog also has ticks but during the application, Bruce only had fleas. The environment has been treated with BUTOX®. The dog goes out to the streets twice a day. The owner took his animal to a veterinary and according to him, the DVM said that it might be a problem with the product. It is unknown if the animal already received FL in the past. No further information is available. UPDATE 7 MAY 2018 – The owner complained that he does not let his animal leaves the house to the streets and Bruce remains with fleas. According to the owner he has been using the product FL for 2 years (1 May 2016 – date chosen at random) and never had any issue. The environment is being treated with BUTOX® on a weekly basis. No further information is available. |
| 02-May-2018 | UAE; 18BR003429; SC; Brazil | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 28-Mar-2018 | 18-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one cat of unknown signalment was treated with FRONTLINE (unsubstantiated) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 28 Mar 2018 and 18 Apr 2018, for ear mite treatment. Lack of efficacy suspected because 'there was no improvement'. This is the extent of the information available. |
| 03-May-2018 | UAE; 18BR003431; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 18-Apr-2008* | 03-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Leidy, 15 years old, 6 kilogram, canine, female, Mixed Breed, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot 008/17 and exp date JAN 2019, topically, between the shoulder blades), applied by the reporter 15 days ago (18 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her dog. According to the owner, the animal already had fleas 4 days prior to treatment. The environment has been treated with BUTOX®. The owner said that she buys FL for more than 10 years (18 Apr 2008 – estimated date). No further information is available. |
| 03-May-2018 | UAE; 18BR003432; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON | 28-Mar-2018 | 03-May-2018* | 5 Week(s) 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Mia, 9 months old, unknown weight, feline, female, Mixed Breed, received 1 pipette of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 28 Mar 2018, for flea and tick treatment. The owner complained about the lack of efficacy because she continues to |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** Unknown | | | | **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | see fleas and ticks in her cat. According to the owner, animal already had parasites 2 months prior to treatment. The environment has not been treated. It is unknown if the animal already had FL in the past. No further information is available. UPDATE 3 MAY 2018 – SAE case reported on 18BR003492. UPDATE 7 MAY 2018 – FRONTLINE was applied to Mia for the first time. No further information is available. |
| 03-May-2018 | UAE; 18BR003435; RS; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** U **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 15-Mar-2018* | 03-May-2018* | 4 Week(s) 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one Yorkshire of 12 years old and unknown weight, was treated, for the second time, with one vial of FRONTLINE PLUS (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Apr 2018 - chosen at random), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and FL was applied for the first time on date not specified (15 Mar 2018 - chosen at random). No further information is expected. |
| 03-May-2018 | UAE; 18BR003446; SP; Brazil | **Species:** Canine **Breed:** Dachshund **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2016* | 30-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 8 dogs of unknown signalment have been treated with FRONTLINE SPRAY (FL) (lot and exp unknown), by the reporter, on date not specified (30 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the dogs continued to have fleas. This is the extent of the information available for now. UPDATE 7 MAY 2018 - The pet owner was contacted and reported that João, a male Dachshund of 14 kg and unknown age, was treated with FRONTLINE SPRAY, topical, whole body, applied by the reporter on 23 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL has been applied every 25 days (first application was not provided - 1 Jan 2016 chosen at random). Similar cases reported on 18BR003496 to 18BR003502. No further information is expected. |
| 03-May-2018 | UAE; 18BR003447; RS; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2016* | 21-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 2 female dogs of unknown signalment have been treated with one vial each one of FRONTLINE PLUS DOGS (FRONTLINE) (size, lot and exp unknown), by the reporter, on date not specified (20 Apr 2018 chosen at random), for flea treatment. Lack of efficacy suspected because both dogs continued to have fleas. This is the extent of the information available for now. UPDATE 7 MAY 2018 - The pet owner was contacted and reported that Neguinha, a female Poodle of 5 years old and 4 kg, was treated with FL PLUS DOG S (FL) (topical, between the shoulder blades and near to the tail - off label), applied by the reporter on Jan 2018 (1 Jan 2018 - chosen at random), for flea treatment. The environment has been treated with My Pet®. FL has been applied every 3 months (first application was not provided - 1 Jan 2016 chosen at random). Another SLOE case was reported on 18BR003503. The owner also reported that 2 cats were treated with FL and they remain infested by fleas (see cases 18BR003504 and 18BR003505). No further information is expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 03-May-2018 | UAE; 18BR003450; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-Mar-2018* | 1 Week(s) | D-D | Suspected Adverse Event: As reported by the owner, Luque, 5 years old, 4 kilogram, feline, male, Mixed Breed, received 1 pipette of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 2 months ago (03 Mar 2018 – estimated date), for flea control. According to the owner, after application, the animal start scratching fiercely after 1 week from application (10 Mar 2018 – estimated date). The owner adopted 2 older cats and saw in them flea feces then the owner decided to use FL in all her other 5 cats. The environment has been treated with BUTOX®. There are another 4 cats in the same household with similar problem (see cases 18BR003451 to 18BR003454) and the owner also complained about the lack of efficacy on the 2 adopted cats (see cases 18BR003455 and 18BR003456). The owner is not sure if she had already used FL in the past. No further information is available. |
| 03-May-2018 | UAE; 18BR003451; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 5 - 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-Mar-2018* | 1 Week(s) | D-D | Suspected Adverse Event: As reported by the owner, Hope, 2 years old, 5-6 kilogram, feline, male, Mixed Breed, received 1 pipette of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 2 months ago (03 Mar 2018 – estimated date), for flea control. According to the owner, after application, the animal start scratching fiercely after 1 week from application (10 Mar 2018 – estimated date). The owner adopted 2 older cats and saw in them flea feces then the owner decided to use FL in all her other 5 cats. The environment has been treated with BUTOX®. There are another 4 cats in the same household with similar problem (see cases 18BR003450 and 18BR003452 to 18BR003454) and the owner also complained about the lack of efficacy on the 2 adopted cats (see cases 18BR003455 and 18BR003456). The owner is not sure if she had already used FL in the past. No further information is available. |
| 03-May-2018 | UAE; 18BR003452; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-Mar-2018* | 1 Week(s) | D-D | Suspected Adverse Event: As reported by the owner, Chanel, 4 years old, 4 kilogram, feline, female, Mixed Breed, received 1 pipette of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 2 months ago (03 Mar 2018 – estimated date), for flea control. According to the owner, after application, the animal start scratching fiercely after 1 week from application (10 Mar 2018 – estimated date). The owner adopted 2 older cats and saw in them flea feces then the owner decided to use FL in all her other 5 cats. The environment has been treated with BUTOX®. There are another 4 cats in the same household with similar problem (see cases 18BR003450, 18BR003451, 18BR003453 and 18BR003454) and the owner also complained about the lack of efficacy on the 2 adopted cats (see cases 18BR003455 and 18BR003456). The owner is not sure if she had already used FL in the past. No further information is available. |
| 03-May-2018 | UAE; 18BR003453; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products | N/A | 10-Mar-2018* | 1 Week(s) | D-D | Suspected Adverse Event: As reported by the owner, Juca, 6 years old, 4 kilogram, feline, male, Mixed Breed, received 1 pipette of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 2 months ago (03 Mar 2018 – estimated date), for flea control. According to the owner, after application, the animal start scratching fiercely after 1 week from application (10 Mar 2018 – estimated date). The animal also presented skin lesion in 2 spots. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Weight:** 4 kg | | | | **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | The owner treated Juca with NEODEXA® and the animal got better. The owner adopted 2 older cats and saw in them flea feces then the owner decided to use FL in all her other 5 cats. The environment has been treated with BUTOX®. There are another 4 cats in the same household with similar problem (see cases 18BR003450 to 18BR003452 and 18BR003454) and the owner also complained about the lack of efficacy on the 2 adopted cats (see cases 18BR003455 and 18BR003456). The owner is not sure if she had already used FL in the past. No further information is available. |
| 03-May-2018 | UAE; 18BR003454; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 6 - 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-Mar-2018* | 1 Week(s) | D-D | Suspected Adverse Event: As reported by the owner, Atchim, 5 years old, 6 to 8 kilogram, feline, male, Mixed Breed, received 1 pipette of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 2 months ago (03 Mar 2018 – estimated date), for flea control. According to the owner, after application, the animal start scratching fiercely after 1 week from application (10 Mar 2018 – estimated date). The animal also presented erythema. The owner treated Atchim with NEODEXA® and the animal got better. The owner adopted 2 older cats and saw in them flea feces then the owner decided to use FL in all her other 5 cats. The environment has been treated with BUTOX®. There are another 4 cats in the same household with similar problem (see cases 18BR003450 to 18BR003453) and the owner also complained about the lack of efficacy on the 2 adopted cats (see cases 18BR003455 and 18BR003456). The owner is not sure if she had already used FL in the past. No further information is available. |
| 03-May-2018 | UAE; 18BR003455; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 03-May-2018* | 8 Week(s) 5 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Haia, 8 to 9 years old, 5 kilogram, feline, female, Mixed Breed, received 1 pipette of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 2 months ago (03 Mar 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because she saw fleas in her adopted cat. The environment has been treated with BUTOX®. There are another 5 cats in the same household with suspected adverse events (see cases 18BR003450 to 18BR003454) and the owner also complained about the lack of efficacy on another adopted cats (see case 18BR003456). The owner is not sure if she had already used FL in the past. No further information is available. |
| 03-May-2018 | UAE; 18BR003456; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 03-May-2018* | 8 Week(s) 5 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Branquinha, 8 to 9 years old, 5 kilogram, feline, female, Mixed Breed, received 1 pipette of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 2 months ago (03 Mar 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because she saw fleas in her adopted cat. The environment has been treated with BUTOX®. There are another 5 cats in the same household with suspected adverse events (see cases 18BR003450 to 18BR003454) and the owner also complained about the lack of efficacy on another adopted cats (see case 18BR003455). The owner is not sure if she had already used FL in the past. No further information is available. |
| 04-May-2018 | UAE; 18BR003468; | **Species:** Canine **Breed:** Shih Tzu | 1 | 1 | 0 | **Product used:** FIPRONIL | N/A | 28-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Marry, an 18-month-old, 5 kg, female, Shih Tzu, was treated with |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | RS; Brazil | **Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 18.00 Month(s)<br>**Weight:** 5 kg | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | one vial of FRONTLINE PLUS DOG S (FL) (001/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 27 Apr 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation one month prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 04-May-2018 | UAE; 18BR003470; SP; Brazil | **Species:** Canine<br>**Breed:** Shar Pei<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Month(s)<br>**Weight:** 33 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 23-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Julia, a 12-month-old, 33 kg, female, Sharpei, was treated with one vial of FRONTLINE PLUS DOG L (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 22 Apr 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation 20 days prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 04-May-2018 | UAE; 18BR003474; MG; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 75.00 Day(s)<br>**Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 14-Apr-2018* | 29-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Meu, 75 days old, 1 kilogram, feline, female, Mixed Breed, received FRONTLINE SPRAY (FL) (lot and exp date unknown, topically, in the body except the head), applied by the reporter on Sunday (29 Apr 2018 – estimated date) and approximately, 15 days before the last application (14 Apr 2018 – estimated date) only in the kittens, for flea treatment. The owner complained about the lack of efficacy because after the first application, animal only stayed 15 days without fleas and after the second application, the product did not work. The environment has not been treated. There are another 3 cats in the same household with similar problem (see cases 18BR003475 to 18BR003477) and 2 of these cats also had a suspected adverse reaction event (see cases 18BR003478 and 18BR003484). No further information is available. |
| 04-May-2018 | UAE; 18BR003475; MG; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 75.00 Day(s)<br>**Weight:** 0.9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 14-Apr-2018* | 29-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Massani, 75 days old, 0.9 kilogram, feline, female, Mixed Breed, received a dose of FRONTLINE SPRAY 250 mL (FL) (lot and exp date unknown, topically, in the body except the head ), applied by the reporter on sunday (29 Apr 2018 – estimated date) and approximately, 15 days before the last application (14 Apr 2018 – estimated date) only in the kittens, for flea treatment. The owner complained about the lack of efficacy because after the first application, animal only stayed 15 days without fleas and after the second application, the product did not work. The environment has not been treated. There are another 3 cats in the same household with similar problem (see cases 18BR003474, 18BR003476 and 18BR003477) and 2 of these cats also had a suspected adverse reaction event (see cases 18BR003478 and 18BR003484). No further information is available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 04-May-2018 | UAE; 18BR003476; MG; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 75.00 Day(s) **Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 14-Apr-2018* | 29-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Cristal, 75 days old, 1 kilogram, feline, female, Mixed Breed, received FRONTLINE SPRAY (FL) (lot and exp date unknown, topically, in the body except the head), applied by the reporter on Sunday (29 Apr 2018 – estimated date) and approximately, 15 days before the last application (14 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because after the first application, animal only stayed 15 days without fleas and after the second application, the product did not work. The environment has not been treated. There are another 3 cats in the same household with similar problem (see cases 18BR003474, 18BR003475 and 18BR003477), Cristal and another unidentified cat also had a suspected adverse reaction event (see cases 18BR003478 and 18BR003484). No further information is available. |
| 04-May-2018 | UAE; 18BR003477; MG; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 29-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Mimi, 3 years old, 5 kilogram, feline, female, Mixed Breed, received FRONTLINE SPRAY (FL) (lot and exp date unknown, topically, in the body except the head), applied by the reporter on Sunday (29 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because after the application she continues to see fleas in her pet. The environment has not been treated. There are another 3 cats in the same household with similar problem (see cases 18BR003474, 18BR003475 and 18BR003476) and 2 of these cats also had a suspected adverse reaction event (see cases 18BR003478 and 18BR003484). It is unknown if the animal already received FL in the past. No further information is available. |
| 04-May-2018 | UAE; 18BR003478; MG; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 75.00 Day(s) **Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 14-Apr-2018* | 29-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the owner, Cristal, 75 days old, 1 kilogram, feline, female, Mixed Breed, received a dose of FRONTLINE SPRAY 250 mL (FL) (lot and exp date unknown, topically, in the body except the head), applied by the reporter on sunday (29 Apr 2018 – estimated date) for flea treatment. Right after the animal presented hypersalivation and recovered on the same day without treatment. There are another 3 cats in the same household, 4 cases of suspected lack of efficacy (see cases 18BR003474 to 18BR003477) and 1 case of suspected adverse event (see case 18R003484). No further information is available. |
| 04-May-2018 | UAE; 18BR003484; MG; Brazil | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | 14-Apr-2018* | 29-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the owner, an unidentifed cat, received a dose of FRONTLINE SPRAY 250 mL (FL) (lot and exp date unknown, topically, in the body except the head), applied by the reporter on sunday (29 Apr 2018 – estimated date) for flea treatment. Right after the animal presented hypersalivation and recovered without tratment. There are another 3 cats in the same household, 4 cases of suspected lack of efficacy (see cases 18BR003474 to 18BR003477) and 1 case of suspected adverse event (see case 18R003478). No further information is available. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** No (Treatment / vaccination program not respected) | | | | | |
| 07-May-2018 | UAE; 18BR003489; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 25-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Penélope, a female small crossbred dog of 12 years old and 9 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, between the shoulder blades), applied by the reporter on 19 Apr 2018 (estimated date), for flea treatment. Lack of efficacy is suspected because the pet remained with fleas. So, 10 days later (29 Apr 2018), the owner applied one vial of FRONTLINE PLUS DOG S (lot and exp date are unknown), but the pet continued infested by fleas. It is unknown if both products were applied in the past. The environment has been treated with deltamethrin. Similar cases were reported on 18BR003490 and 18BR003491. No further information is expected. |
| 07-May-2018 | UAE; 18BR003490; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 25-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Suzy, a female small crossbred dog of 7 years old and 10 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, between the shoulder blades), applied by the reporter on 19 Apr 2018 (estimated date), for flea treatment. Lack of efficacy is suspected because the pet remained with fleas. So, 10 days later (29 Apr 2018), the owner applied one vial of FRONTLINE PLUS DOG S (lot and exp date are unknown), but the pet continued infested by fleas. It is unknown if FL was applied in the past. The environment has been treated with deltamethrin. Similar cases were reported on 18BR003489 and 18BR003491. No further information is expected. |
| 07-May-2018 | UAE; 18BR003491; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 25-Apr-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female small crossbred dog of 4 years old and 8 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, between the shoulder blades), applied by the reporter on 19 Apr 2018 (estimated date), for flea treatment. Lack of efficacy is suspected because the pet remained with fleas. So, 10 days later (29 Apr 2018), the owner applied one vial of FRONTLINE PLUS DOG S (lot and exp date are unknown), but the pet continued infested by fleas. It is unknown if FL was applied in the past. The environment has been treated with deltamethrin. Similar cases were reported on 18BR003489 and 18BR003491. No further information is expected. |
| 03-May-2018 | UAE; 18BR003492; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the** | 28-Mar-2018 | 29-Mar-2018* | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Mia, a 9-month-old, female, mixed breeds cat (weight unknown), was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, for the first time, on 28 Mar 2018, for flea and tick treatment. Following product application (time to onset not specified), the cat presented with application site hair discolouration: Mia's hair coat is white and the application site was orange/reddish. UPDATE 7 MAY 2018 - The owner was not sure if the hair coat discolouration was an adverse reaction to FL. Mia recovered by her own on date unknown. No other signs noticed. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **product used ok?:** Yes | | | | | SLOE case reported on 18BR003432. There is no further information expected. |
| 07-May-2018 | UAE; 18BR003494; SP; Brazil | **Species:** Canine **Breed:** Rottweiler **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 55 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 07-May-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Akira, 6 years old, 55 kilogram, canine, female, Rottweiler, received 1 pipette of FRONTLINE PLUS DOG XL (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 23 Apr 2018, for tick treatment. The owner complained about the lack of efficacy because she continues to see ticks in her dog. According to the owner, the animal already had ticks 7 days prior to treatment. The environment has not been treated. It is unknown if the animal already had FL in the past. No further information is available. |
| 03-May-2018 | UAE; 18BR003496; SP; Brazil | **Species:** Canine **Breed:** Pit Bull **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 03-May-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Zeus, a male Pit Bull of 1 kg and unknown age, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on 23 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL was applied in the past. Similar cases reported on 18BR003446, 18BR003497 to 18BR003502. No further information is expected. |
| 03-May-2018 | UAE; 18BR003497; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 12 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2016* | 03-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, John, a male medium crossbred dog of 12 kg and unknown age, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on 23 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL has been applied every 25 days (first application was not provided - 1 Jan 2016 chosen at random). Similar cases reported on 18BR003446, 18BR003496, 18BR003498 to 18BR003502. No further information is expected. |
| 03-May-2018 | UAE; 18BR003498; SP; Brazil | **Species:** Canine **Breed:** Terrier Breeds (500 Series) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination | 01-Jan-2016* | 03-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bebe, a female Brazilian Terrier of 7 kg and unknown age, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on 23 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL has been applied every 25 days (first application was not provided - 1 Jan 2016 chosen at random). Similar cases reported on 18BR003446, 18BR003496, 18BR003497, 18BR003499 to 18BR003502. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | program not respected) | | | | | |
| 03-May-2018 | UAE; 18BR003499; SP; Brazil | **Species:** Canine **Breed:** Doberman **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 40 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2016* | 03-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Thuca, a female Doberman crossbred with Fila of 40 kg and unknown age, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on 23 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL has been applied every 25 days (first application was not provided - 1 Jan 2016 chosen at random). Similar cases reported on 18BR003446, 18BR003496 to 18BR003498, 18BR003500 to 18BR003502. No further information is expected. |
| 03-May-2018 | UAE; 18BR003500; SP; Brazil | **Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 40 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2016* | 03-May-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Troia, a female Pit Bull of 40 kg and 10 years old, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on 23 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL has been applied every 25 days (first application was not provided - 1 Jan 2016 chosen at random). Similar cases reported on 18BR003446, 18BR003496 to 18BR003499, 18BR003501 and 18BR003502. No further information is expected. |
| 03-May-2018 | UAE; 18BR003501; SP; Brazil | **Species:** Canine **Breed:** Dachshund **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2016* | 03-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Ruth, a female Dachshund of 9 kg and 6 years old, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on 23 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL has been applied every 25 days (first application was not provided - 1 Jan 2016 chosen at random). Similar cases reported on 18BR003446, 18BR003496 to 18BR003500 and 18BR003502. No further information is expected. |
| 03-May-2018 | UAE; 18BR003502; SP; Brazil | **Species:** Canine **Breed:** Dachshund **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous | 01-Jan-2016* | 03-May-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Diana, a female Dachshund of 10 kg and 6 years old, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on 23 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL has been applied every 25 days (first application was not provided - 1 Jan 2016 chosen at random). Similar cases |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | reported on 18BR003446, 18BR003496 to 18BR003501. No further information is expected. |
| 03-May-2018 | UAE; 18BR003503; RS; Brazil | **Species:** Canine **Breed:** Dachshund **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2016* | 04-May-2018* | 4 Month(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Meg, a female Dachshund of 3 years old and 3.5 kg, was treated with FL PLUS DOG S (FL) (lot and exp date are unknown, topical, between the shoulder blades and near to the tail - off label), applied by the reporter on Jan 2018 (1 Jan 2018 - chosen at random), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with My Pet® every week. FL has been applied every 3 months (first application was not provided - 1 Jan 2016 chosen at random). Another SLOE case was reported on 18BR003447. The owner also reported that 2 cats were treated with FL and they remain infested by fleas (see cases 18BR003504 and 18BR003505). No further information is expected. |
| 07-May-2018 | UAE; 18BR003504; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jul-2017* | 04-May-2018* | 4 Month(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Salém, a male mixed breed cat of 1 year old and unknown weight, was treated with FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, between the shoulder blades and near to the tail - off label), applied by the reporter on Jan 2018 (1 Jan 2018 - chosen at random), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with My Pet® every week. FL has been applied every 3 months (first application was not provided - 1 Jul 2017 chosen at random). Another SLOE case was reported on 18BR003505. The owner also reported that 2 dogs were treated with FL and they remain infested by fleas (see cases 18BR003447 and 18BR003503). No further information is expected. |
| 07-May-2018 | UAE; 18BR003505; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination | 01-Jul-2017* | 04-May-2018* | 4 Month(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Jolly, a female mixed breed cat of 1 year old and unknown weight, was treated with FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, between the shoulder blades and near the tail - off label), applied by the reporter on Jan 2018 (1 Jan 2018 - chosen at random), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with My Pet® every week. FL has been applied every 3 months (first application was not provided - 1 Jul 2017 chosen at random). Another SLOE case was reported on 18BR003504. The owner also reported that 2 dogs were treated with FL and they remains infested by fleas (see cases 18BR003447 and 18BR003504). No further information is expected. |

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| | | | | | | program not respected) | | | | | |
| 07-May-2018 | UAE; 18BR003506; SP; Brazil | **Species:** Canine **Breed:** Dachshund **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 9 kg | 3 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 07-May-2018* | 26 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Cascão, 7 years old, 9 kilogram, canine, male, Dachshund, received approximately 1/3 from the pipette of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 11 Apr 2018, for tick treatment. The owner complained about the lack of efficacy because sometimes she finds ticks in her pets. According to the owner FL was applied as soon as she noticed the first ticks after the bath. The owner also have another 2 dogs and she fractionated 1 pipette for all 3 dogs using a syringe. Only Cascão has ticks. No further information is available. |
| 07-May-2018 | UAE; 18BR003510; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 16 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2018* | 25-Apr-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bonito, a male medium crossbred dog of unknown age and 16 kg, was treated, for the second time, with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 11 Apr 2018, for flea treatment. Lack of efficacy is suspected because fleas were found on the pet in the end of April. The environment has not been treated and FL was applied for the first time 5 months ago with no issue (1 Jan 2018 - chosen at random). There are 2 untreated cats in the same household. No further information is expected. |
| 07-May-2018 | UAE; 18BR003513; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 08-Mar-2018 | 1 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Malu, 12 years old, 10 kilogram, canine, female, Mixed Breed, received a dose of FRONTLINE SPRAY® (FS) (lot and exp date unknown, topically, in the whole body), applied by the reporter 2 months ago (7 Mar 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because she said that FS did not work. The environment has been treated with K-OTHRINE® for 3 months. There are another 3 dogs in the same household with similar problem (see cases 18BR003514 to 18BR003516). One of the dogs was recently treated with FRONTLINE PLUS DOG® and the owner suspects of lack of efficacy (see case 18BR003517). No further information is available. |
| 07-May-2018 | UAE; 18BR003514; SP; Brazil | **Species:** Canine **Breed:** Basset Hound **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 08-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Luma, 10 years old, 14 kilogram, canine, female, Basset Hound, received a dose of FRONTLINE SPRAY® (FS) (lot and exp date unknown, topically, in the whole body), applied by the reporter 2 months ago (7 Mar 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because she said that FS did not work. The environment has been treated with K-OTHRINE® for 3 months. There are another 3 dogs in the same household with similar problem (see cases 18BR003513, 18BR003515 and 18BR003516). One of the dogs was recently treated with FRONTLINE PLUS DOG® and the owner suspects of lack of efficacy (see case 18BR003517). No further information is available. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 07-May-2018 | UAE; 18BR003515; SP; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 08-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Boris, 3 years old, 5 kilogram, canine, male, Lhasa Apso, received a dose of FRONTLINE SPRAY® (FS) (lot and exp date unknown, topically, in the whole body), applied by the reporter 2 months ago (7 Mar 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because she said that FS did not work. The environment has been treated with K-OTHRINE® for 3 months. There are another 3 dogs in the same household with similar problem (see cases 18BR003513, 18BR003514 and 18BR003516). One of the dogs was recently treated with FRONTLINE PLUS DOG® and the owner suspects of lack of efficacy (see case 18BR003517). No further information is available. |
| 07-May-2018 | UAE; 18BR003516; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 08-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Bia, 4 months old, 1.5 kilogram, canine, female, Shih Tzu, received a dose of FRONTLINE SPRAY® (FS) (lot and exp date unknown, topically, in the whole body), applied by the reporter 2 months ago (7 Mar 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because she said that FS did not work. The environment has been treated with K-OTHRINE® for 3 months. There are another 3 dogs in the same household with similar problem (see cases 18BR003513 to 18BR003515). One of the dogs was recently treated with FRONTLINE PLUS DOG® and the owner suspects of lack of efficacy (see case 18BR003517). No further information is available. |
| 07-May-2018 | UAE; 18BR003517; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 07-May-2018* | 8 Week(s) 5 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Bia, 4 months old, 1.5 kilogram, canine, female, Shih Tzu, received a dose of FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter 15 days ago (22 Apr 2018 – estimated date), for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her pet. The environment has been treated with K-OTHRINE® for 3 months. There are another 3 dogs in the same household, who were treated with FRONTLINE SPRAY and the owner suspects from lack of efficacy (see cases 18BR003513 to 18BR003516). Bia was also treated with FRONTLINE SPRAY. The owner said that she used a product from another company and the dog does not have fleas anymore. No further information is available. |
| 06-May-2018 | UAE; 18BR003520; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 05-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, her dog and cats were treated with FRONTLINE but continued to have fleas. UPDATE 7 MAY 2018 – Felix, an 18-month-old, 6 kg, male, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 4 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 5 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the pet in the past. There's a history of a recently rescued cat, infested by fleas, which stayed at the household for 2 hours. 5 other pets of the same household that are also on FRONTLINE were reported on 18BR003521, 18BR003522, 18BR003523, 18BR003524 and 18BR003525. No further information is available. |
| 06-May-2018 | UAE; 18BR003521; | **Species:** Feline **Breed:** Feline | 1 | 1 | 0 | **Product used:** FIPRONIL | N/A | 05-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, her dog and cats were treated with FRONTLINE |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | SP; Brazil | mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 3.5 kg | | | | 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | but continued to have fleas. UPDATE 7 MAY 2018 – Juju, a 4-year-old, 3.5 kg, female, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 4 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 5 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the pet in the past. There's a history of a recently rescued cat, infested by fleas, which stayed at the household for 2 hours. 5 other pets of the same household that are also on FRONTLINE were reported on 18BR003520, 18BR003522, 18BR003523, 18BR003524 and 18BR003525. No further information is available. |
| 06-May-2018 | UAE; 18BR003522; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 10.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 05-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, her dog and cats were treated with FRONTLINE but continued to have fleas. UPDATE 7 MAY 2018 – Perola, a 10-year-old, 6 kg, female, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 4 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 5 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the pet in the past. There's a history of a recently rescued cat, infested by fleas, which stayed at the household for 2 hours. 5 other pets of the same household that are also on FRONTLINE were reported on 18BR003520, 18BR003521, 18BR003523, 18BR003524 and 18BR003525. No further information is available. |
| 06-May-2018 | UAE; 18BR003523; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 14.00 Year(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 05-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, her dog and cats were treated with FRONTLINE but continued to have fleas. UPDATE 7 MAY 2018 – Bebe, a 14-year-old, 2 kg, female, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 4 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 5 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the pet in the past. There's a history of a recently rescued cat, infested by fleas, which stayed at the household for 2 hours. 5 other pets of the same household that are also on FRONTLINE were reported on 18BR003520, 18BR003521, 18BR003522, 18BR003524 and 18BR003525. No further information is available. |
| 06-May-2018 | UAE; 18BR003524; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 17.00 Year(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 05-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, her dog and cats were treated with FRONTLINE but continued to have fleas. UPDATE 7 MAY 2018 – Tigra, a 17-year-old, 2 kg, female, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 4 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 5 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the pet in the past. There's a history of a recently rescued cat, infested by fleas, which stayed at the household for 2 hours. 5 other pets of the same household that are also on FRONTLINE were reported on 18BR003520, 18BR003521, 18BR003522, 18BR003523 and 18BR003525. No further information is available. |
| 06-May-2018 | UAE; | **Species:** Canine | 1 | 1 | 0 | **Product used:** | 05-May-2018 | 06-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | 18BR003526; RJ; Brazil | **Breed:** Great Dane **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 50 kg | | | | FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | via e-mail, her Great Dane was treated with one vial of FRONTLINE PLUS DOG XL (FL) on 5 May 2018, but continued to have fleas and ticks. UPDATE 7 MAY 2018 – Scooby, male, 7 years old, 50 kg, was treated with FL (016/17, Mar 2019), topic, back, by the reporter for the first time. Flea and tick infestation one week prior to FL, environment not treated, stray dogs in the neighborhood. There are more 5 non treated dogs in the same household. No further information is available. UPDATE 10 MAY 2018 - According to the owner, NEXGARD was used prior to FL with no issue. The reporter continues to see fleas and ticks on her pet after FL application (pictures were received). No further information is expected. UPDATE 14 MAY 2018 - The owner still believes that FL is not working as well as she expected. There is no further information known. |
| 07-May-2018 | UAE; 18BR003532; SP; Brazil | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Month(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 29-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mia, a 14-month-old, 5 kg, female cat (breed unknown), was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 28 Apr 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 2 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the cat in the past. No further information is available. |
| 05-May-2018 | UAE; 18BR003534; SP; Brazil | **Species:** Canine **Breed:** Schnauzer **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 15-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 2 dogs of unknown signalment were treated with one vial of FRONTLINE 'pipette' each (FL) (lot, exp date, route and location are unknown), applied by the reporter on 1 Apr 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). It is unknown if the environment has been treated. This is the extent of the information available. UPDATE 14 MAY 2018 – The user reported a third animal and differentiated all animals involved. The owner reported that: Luna, 3 years old, 5 kilogram, canine, female, Schnauzer, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot, and exp date unknown, topically, between the shoulder blades ), administered by the owner 2 months ago (14 Mar 2018 – estimated date) for tick treatment. The owner complained that she continues to see ticks in her dog. According to the owner, animal already had ticks 2 weeks prior to treatment. The owner said that FL is used accordingly to the need approximately, every 3 months The environment has been treated with BUTOX®. There are another 2 dogs in the same household with similar problem (see cases 18BR003699 and 18BR003700). No fleas were reported during the update. No further information is available. |
| 08-May-2018 | UAE; 18BR003538; CE; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | N/A | 25-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Spike, a 12-year-old, 12 kg, male, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (009/16, Nov 2018), topic, base of skull and btw the shoulder blades, by the reporter, 2 |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Year(s)<br>**Weight:** 12 kg | | | | 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | weeks ago (24 Apr 2018), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation 2 months prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 08-May-2018 | UAE; 18BR003539; SP; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Year(s)<br>**Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2016* | 08-May-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Panqueca, a 12-year-old, 8 kg, female, Lhasa Apso, was treated with one vial of FRONTLINE PLUS DOG S (FL) (014/17, Feb 2019), topic, base of skull and btw the shoulder blades, by the reporter, 2 weeks ago (24 Apr 2018), for tick prevention. Lack of efficacy suspected because the dog is currently infested by ticks. FL is usually applied every 2 months (first dose on date not specified – 1 Jan 2016 chosen at random), environment not treated. No further information is available. |
| 08-May-2018 | UAE; 18BR003540; RS; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 11 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 29-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Brisa, a 2-year-old, 11 kg, female, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 28 Apr 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 1 day prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 08-May-2018 | UAE; 18BR003545; PR; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 16 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2016* | 03-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Vaco, an 8-year-old, 16 kg, male, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (019/17, Mar 2019), topic, base of skull and btw the shoulder blades, by the reporter, on 2 May 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation one week prior to FL, environment not treated. FRONTLINE was usually applied every 6 months with no issues (first dose on date not specified – 1 Jan 2016 chosen at random). No further information is available. |
| 07-May-2018 | UAE; 18BR003549; SP; Brazil | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other | 02-May-2018 | 06-May-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Dodge, 5 to 6 months old, 7.5 kilogram, canine, male, Mixed Breed (Beagle x Labrador Retriever), received for the first time 1 pipette of FRONTLINE PLUS DOG S (FL) (lot 014/17 and exp date unknown, topically, between the shoulder blades), applied by the reporter on 2 May 2018, for tick treatment. The owner complained about the lack of efficacy because after 4 days (6 May 2018) he |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Month(s)<br>**Weight:** 7.5 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | found ticks on his animal. The environment has been treated this weekend (6 to 7 May 2018) with BUTOX®. According to the owner, Dodge is not infested by ticks anymore. The dog does not have contact with the street. The owner also suspects of an adverse event (see case 18BR003550). No further information is available. |
| 07-May-2018 | UAE; 18BR003550; SP; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Month(s)<br>**Weight:** 7.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Unknown Vaccine; Unknown Vermifuge;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 02-May-2018 | 05-May-2018 | 3 Day(s) | D-D | Suspected Adverse Event: As reported by the owner, Dodge, 5 to 6 months old, 7.5 kilogram, canine, male, Mixed Breed (Beagle with Labrador), received for the first time 1 pipette of FRONTLINE PLUS DOG S (FL) (lot 014/17 and exp date unknown, topically, between the shoulder blades), applied by the reporter on 2 May 2018, for tick treatment. According to the owner, the animal also received a dose from an unknown vaccine for primary vaccination protocol and vermifuge on unspecified date (01 May 2018 – date chosen at random). The owner said that 3 days after the application (5 May 2018), he noticed hair loss in his dog. The dog was not taken to the veterinary after this occurrence. The owner also suspects of lack of efficacy (see case 18BR003549). No further information is available. |
| 05-May-2018 | UAE; 18BR003555; -; Brazil | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 30-Apr-2018* | 30 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female dog of unknown signalment was treated with FRONTLINE (unsubstantiated) (lot and exp unknown), by the reporter, on final Mar 2018 (31 Mar 2018 chosen at random), for flea treatment. On final Apr 2018 the dog was infested by fleas again, so lack of efficacy was suspected. The dog was treated with another company's product on date not specified, however she continued to have fleas. This is the extent of the information available. UPDATE 11 MAY 2018 - According to the owner, the product applied is FRONTLINE PLUS (unsubstantiated). No further information is available. |
| 08-May-2018 | UAE; 18BR003561; SP; Brazil | **Species:** Canine<br>**Breed:** Pinscher (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Month(s)<br>**Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 08-May-2018* | 4 Month(s) 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lili, a female Pinscher of approximately 7 months old and 2.5 kg, was treated with one vial of FRONTLINE SPOT-ON DOG S (FL) (004/17 and unknown exp date, topical, btw the shoulder blades), applied by the reporter 'more than 30 days ago' (1 Apr 2018 - chosen at random). Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 07-May-2018 | UAE; 18BR003562; RS; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 01-Apr-2018* | 07-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Jimmy Handrix, a male small crossbred dog of 3 years old and 10 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (009/16, Jun 2018, topical, whole body), applied by the reporter on 5 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin monthly. FL was applied for the first time on date not specified (1 Apr 2018 - chosen at random). Similar cases reported on 18BR003563 to 18BR003569. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Yes | | | | | |
| 07-May-2018 | UAE; 18BR003563; RS; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 26 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Apr-2018* | 07-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Billy, a male large crossbred dog of 14 years old and 26 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (009/16, Jun 2018, topical, whole body), applied by the reporter on 5 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin monthly. FL was applied for the first time on date not specified (1 Apr 2018 - chosen at random). Similar cases reported on 18BR003562, 18BR003564 to 18BR003569. No further information is expected. |
| 07-May-2018 | UAE; 18BR003564; RS; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 1.50 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Apr-2018* | 07-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Nega, a female small crossbred dog of 1.5 year old and 8 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (009/16, Jun 2018, topical, whole body), applied by the reporter on 5 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin monthly. FL was applied for the first time on date not specified (1 Apr 2018 - chosen at random). Similar cases reported on 18BR003562, 18BR003563, 18BR003565 to 18BR003569. No further information is expected. |
| 07-May-2018 | UAE; 18BR003565; RS; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Apr-2018* | 07-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Mel, a female small crossbred dog of 9 years old and 3.5 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (009/16, Jun 2018, topical, whole body), applied by the reporter on 5 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin monthly. FL was applied for the first time on date not specified (1 Apr 2018 - chosen at random). Similar cases reported on 18BR003562 to 18BR003564, 18BR003566 to 18BR003569. No further information is expected. |
| 07-May-2018 | UAE; 18BR003566; RS; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 28 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Apr-2018* | 07-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Chow, a female large crossbred dog of 5 years old and 28 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (009/16, Jun 2018, topical, whole body), applied by the reporter on 5 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin monthly. FL was applied for the first time on date not specified (1 Apr 2018 - chosen at random). Similar cases reported on 18BR003562 to 18BR003565, 18BR003567 to 18BR003569. No further information is expected. |
| 07-May-2018 | UAE; 18BR003567; RS; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 16 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the** | 01-Apr-2018* | 07-May-2018* | 2 Day(s) | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Marron, a female medium crossbred dog of 5 years old and 16 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (009/16, Jun 2018, topical, whole body), applied by the reporter on 5 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin monthly. FL was applied for the first time on date not specified (1 Apr 2018 - chosen at random). Similar cases reported on 18BR003562 to 18BR003566, |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **product used ok?:** Yes | | | | | 18BR003568 and 18BR003569. No further information is expected. |
| 07-May-2018 | UAE; 18BR003568; RS; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 22 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Apr-2018* | 07-May-2018* | 2 Day(s) | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Preta, a female large crossbred dog of 5 years old and 22 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (009/16, Jun 2018, topical, whole body), applied by the reporter on 5 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin monthly. FL was applied for the first time on date not specified (1 Apr 2018 - chosen at random). Similar cases reported on 18BR003562 to 18BR003567 and 18BR003569. No further information is expected. |
| 07-May-2018 | UAE; 18BR003569; RS; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Apr-2018* | 07-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Coco, a female small crossbred dog of 9 years old and 4 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (009/16, Jun 2018, topical, whole body), applied by the reporter on 5 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin monthly. FL was applied for the first time on date not specified (1 Apr 2018 - chosen at random). Similar cases reported on 18BR003562 to 18BR003568. No further information is expected. |
| 07-May-2018 | UAE; 18BR003570; BA; Brazil | **Species:** Canine **Breed:** Canine Other **Sex:** F **Sex qualifier:** Lactating **Age:** 21.00 Month(s) **Weight:** 37 kg | 7 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 06-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the owner, Luna, 21 months old, 37 kilogram, canine, female, lactating, Argentine Dogo, received a dose of FRONTLINE SPRAY 100 mL (FL) (lot 003/17 and exp date unknown, topically, in the back), applied by the owner on 6 May 2018, for tick treatment. According to the owner the animal was in good health prior to treatment. Luna is lactating 6 puppies and the owner noticed 1 tick in Luna and another tick in one of the puppies. He went to a store and the shopkeeper recommended FL to him and he applied in all dogs. Luna, also licked the puppies after FL was applied. The animal presented apathy, lethargy and irregular breathing (6 May 2018 - date chosen atrandom). The owner contacted a DVM and was oriented to give PEDIALITE® and an antitoxic. The owner applied the products prescribed but continues to notice lethargy and fever on Luna. The owner was used to BRAVECTO® and never had any issue with medication before. No further information is available. |
| 09-May-2018 | UAE; 18BR003581; SP; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 09-May-2018* | 23 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pucca, a female Poodle Toy of 9 years old and 2 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 16 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated, and it is unknown if FL has previously been applied. No further information is expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 08-May-2018 | UAE; 18BR003585; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 12 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Feb-2018* | 01-Mar-2018* | 4 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lucky, a 12-month-old, 12 kg, male, Yorkshire Terrier, was treated with FRONTLINE (unsubstantiated) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, for the first time, on early Feb 2018 (1 Feb 2018 chosen at random), for tick treatment. Lack of efficacy suspected because the dog had tick-borne disease. Diagnosis based on CBC test results. Lucky was treated and recovered. On Apr 2018, the dog was treated again with FRONTLINE, but continued to have ticks (see 18BR003586). No further information is available. |
| 08-May-2018 | UAE; 18BR003586; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Month(s) **Weight:** 12 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 01-Feb-2018* | 01-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lucky, a 12-month-old, 12 kg, male, Yorkshire Terrier, was treated with FRONTLINE (unsubstantiated) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on final Apr 2018 (30 Apr 2018 chosen at random), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks . Tick infestation prior to FL, environment treated with Butox. FRONTLINE was applied once, on Feb 2018, but the dog got tick-borne disease (see 18BR003585). No further information is available. |
| 08-May-2018 | UAE; 18BR003589; SP; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a 14-year-old, 5 kg, female, Lhasa Apso, was treated with FRONTLINE SPRAY (FL) (010/16, Jun 2018), topic, whole body, by the reporter, on 10 Apr 2018 approximately, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 20 days prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. 2 other pets of the same household that are also on FL were reported on 18BR003590 and 18BR003591. No further information is available. |
| 08-May-2018 | UAE; 18BR003590; SP; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nika, a 7-year-old, 5 kg, female, Lhasa Apso, was treated with FRONTLINE SPRAY (FL) (010/16, Jun 2018), topic, whole body, by the reporter, on 10 Apr 2018 approximately, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 20 days prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. 2 other pets of the same household that are also on FL were reported on 18BR003589 and 18BR003591. No further information is available. |
| 08-May-2018 | UAE; 18BR003591; | **Species:** Feline | 1 | 1 | 0 | **Product used:** FIPRONIL | N/A | 10-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Perola, a 4-year-old, 10 kg, female, mixed breeds cat, was treated |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | SP; Brazil | **Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 10 kg | | | | SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | with FRONTLINE (unsubstantiated) (lot and exp unknown), topic, by the reporter, on 10 Apr 2018 approximately, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 20 days prior to FRONTLINE, environment treated with Butox. It is unknown if FRONTLINE was applied to the cat in the past. 2 other pets of the same household that are also on FRONTLINE were reported on 18BR003589 and 18BR003590. No further information is available. |
| 08-May-2018 | UAE; 18BR003593; RJ; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 15.00 Year(s)<br>**Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 08-Apr-2018* | 08-Apr-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Kebeck, a 15-year-old, 14 kg, male, crossbred dog, was treated with FRONTLINE SPRAY (FL) (007/16, Jun 2018), topic, whole body, by the reporter, every week starting one month ago (8 Apr 2018), for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation one month prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 08-May-2018 | UAE; 18BR003594; MG; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 16-Apr-2018 | 08-May-2018* | 22 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Theo, a male Lhasa Apso of 3 kg and unknown age, received, for the first time, one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 16 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. No further information is expected. |
| 08-May-2018 | UAE; 18BR003597; SP; Brazil | **Species:** Canine<br>**Breed:** Maltese<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2016* | 08-May-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Loa, a female Maltese of 7 years old and 4 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, base of skull, back and paws), applied by the reporter on 30 Apr 2018, for flea and tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has not been treated and FL was applied in the past with no issue (1 Jan 2016 - chosen at random). There are 3 dogs and 1 cat in this household that were not treated with FL and it is unknown if they were treated with another product against ectoparasites. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 08-May-2018 | UAE; 18BR003603; SP; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 09-Jan-2018 | 15-Mar-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Ully, a male Lhasa Apso of 6 years old and 8 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the owner on 20 Apr 2018, fot flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and FL was applied for the first time one 9 Jan 2018 and for the second time on 12 Mar 2018. Fleas have been found since the second application of FL. No further information is expected. |
| 09-May-2018 | UAE; 18BR003604; RS; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 09-May-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the owner, Penelope, 11 years old, 3.5 kilogram, canine, female, Lhasa Apso, received a dose of FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the reporter on 27 Apr 2018, for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her animal. It is unknown if the environment has been treated with a specific product. The dog goes out to the streets. It is unknown if the animal already had FL before. No further information is available. |
| 09-May-2018 | UAE; 18BR003608; SP; Brazil | **Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL 6.01% / PERMETHRIN 44.88% SPOT ON SOLUTION; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 06-May-2018* | 11 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Buddy, an 8-year-old, 5 kg, male, Maltese, was treated with one vial of FRONTLINE PLUS DOG S (lot and exp unknown), 2 weeks ago (25 Apr 2018), and one vial of FRONTLINE TRI-ACT (size, lot and exp unknown), on 5 May 2018, both topic, base of skull and btw the shoulder blades, by the reporter, for flea treatment. Lack of efficacy suspected because the dog is still infested by fleas. Flea infestation 5 days prior to the first dose of FRONTLINE, environment not treated, outdoor access. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 09-May-2018 | UAE; 18BR003609; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 02-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Maria Joakina, a 7-year-old, 4 kg, female, Yorkshire Terrier, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter 8 days ago (1 May 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 15 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 09-May-2018 | UAE; 18BR003614; | **Species:** Canine | 1 | 1 | 0 | **Product used:** FIPRONIL | N/A | 20-Apr-2018* | 5 Day(s) | D-B | Suspected Adverse Event: As reported by the pet owner, Ariel, a female Shih Tzu of 3 months old and 3.5 kg, was treated with |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | RJ; Brazil | **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 3.5 kg | | | | SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | | | | | FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, unnknown location), applied by an unknown person on 15 Apr 2018. On date not specified, the pet presented apathy. He was taken to the vet and a CBC test showed some alterations (details are unknown). The pet was diagnosed with hepatic insufficiency. SAM-e® was prescribed by the vet, who doesn't suspect that FL caused this problem. This is the extent of the information available. |
| 09-May-2018 | UAE; 18BR003616; RS; Brazil | **Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 09-May-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female Maltese of 11 years old (other signalment is unknown), received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), administered by the reporter on date not specified (1 May 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet is infested by fleas. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. No further information is expected. UPDATE 16 MAY 2018 - Brigitte, 3 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL), topic, base of skull and btw the shoulder blades. Flea infestation one week prior to FL, environment treated with K-Othrine and My Pet. It is unknown if FRONTLINE was applied to the dog in the past. UPDATE 17 MAY 2018 - via social media, the owner reported had discovered one tick on Brigitte on date unknown. This is the extent of the information available. |
| 09-May-2018 | UAE; 18BR003618; SP; Brazil | **Species:** Canine **Breed:** Chowchow **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 08-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), administered by the reporter on date not specified (1 May 2018 - estimated date), for tick treatment. Lack of efficacy is suspected because the pet is infested by ticks. This is the extent of the information available. UPDATE 11 MAY 2018 – Tom, a 3-month-old, 8 kg, male, Chow Chow, was treated with one vial of FRONTLINE PLUS DOG S (FL), topic, base of skull and btw the shoulder blades, on 7 May 2018. Environment treated. It is unknown if FRONTLINE was applied to the pup in the past. There is one other dog in the same household, but it is unknown if it was treated. No further information is available. |
| 10-May-2018 | UAE; 18BR003623; SP; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 05-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Suki, a 10-year-old, 35 kg, female, crossbred dog, was treated with one vial of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 4 May 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 10-May-2018 | UAE; 18BR003625; SP; Brazil | **Species:** Feline **Breed:** Siamese **Sex:** M **Sex qualifier:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON | 01-Jan-2017* | 13-Oct-2017* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Elvis, a 3-year-old, 2.5 kg, male, Siamese cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on Oct 2017 (12 Oct 2017 chosen at random), for flea treatment. Lack |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Age:** 3.00 Year(s)<br>**Weight:** 2.5 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | of efficacy suspected because the cat continued to have fleas . Other details were not provided. FRONTLINE was applied in the past with no issues (date not specified – 1 Jan 2017 chosen at random). 2 other cats of the same household that were also on FL were reported on 18BR003626 and 18BR003627. Since FL did not work, FRONTLINE SPOT-ON CAT was applied on Feb 2018 but did not work also (see 18BR003628). No further informaiton is available. |
| 10-May-2018 | UAE; 18BR003626; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 13-Oct-2017* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Jimi, a 5-year-old, 3 kg, male, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on Oct 2017 (12 Oct 2017 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas . Other details were not provided. FRONTLINE was applied in the past with no issues (date not specified – 1 Jan 2017 chosen at random). 2 other cats of the same household that were also on FL were reported on 18BR003625 and 18BR003627. Since FL did not work, FRONTLINE SPOT-ON CAT was applied on Feb 2018 but did not work also (see 18BR003629). No further informaiton is available. |
| 10-May-2018 | UAE; 18BR003627; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 13-Oct-2017* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Emili, a 5-year-old, 5 kg, female, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on Oct 2017 (12 Oct 2017 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Other details were not provided. FRONTLINE was applied in the past with no issues (date not specified – 1 Jan 2017 chosen at random). 2 other cats of the same household that were also on FL were reported on 18BR003625 and 18BR003626. Since FL did not work, FRONTLINE SPOT-ON CAT was applied on Feb 2018 but did not work also (see 18BR003630). No further informaiton is available. |
| 10-May-2018 | UAE; 18BR003628; SP; Brazil | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 13-Feb-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Elvis, a 3-year-old, 2.5 kg, male, Siamese cat, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (011/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 12 Feb 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation prior to FL, environment treated with Fleegard. FRONTLINE was applied on Oct 2018 but did not work (see 18BR003625). 2 other cats of the same household that were also on FL were reported on 18BR003629 and 18BR003630. No further information is available. |
| 10-May-2018 | UAE; 18BR003629; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 01-Jan-2017* | 13-Feb-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Jimi, a 5-year-old, 3 kg, male, mixed breeds cat, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (011/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 12 Feb 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation prior to FL, environment treated with Fleegard. FRONTLINE was applied on Oct 2018 but did not work (see 18BR003626). 2 other cats of the same household that were also on FL were reported on 18BR003628 and 18BR003630. No further |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **ok?:** Yes | | | | | information is available. |
| 10-May-2018 | UAE; 18BR003630; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 13-Feb-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Emili, a 5-year-old, 5 kg, female, mixed breeds cat, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (011/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 12 Feb 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation prior to FL, environment treated with Fleegard. FRONTLINE was applied on Oct 2018 but did not work (see 18BR003627). 2 other cats of the same household that were also on FL were reported on 18BR003628 and 18BR003629. No further information is available. |
| 09-May-2018 | UAE; 18BR003632; SC; Brazil | **Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Unknown **Age:** 30.00 Month(s) **Weight:** 45 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 08-May-2017* | 08-May-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner: Blair, 30 months old, 45 kilogram, canine,female, Golden Retriever, received FRONTLINE PLUS DOG XL (FL) (lot 016/17 and exp date unknown, topically , between the shoulder blades), applied by the owner on 8 May 2018, for tick treatment. The owner complained about the lack of efficacy of FL because she continues to see ticks in her animal. According to the owner, she applied FL as soon as she noticed ticks in her animal. The environment has been treated with BUTOX® and according to the owner it is full of ticks over the walls and ceiling of her kennel. The owner believes the animal got ticks during the bath. It is not the first time the owner uses FL ( 8 May 2017 – date chosen at random). No further information is available. |
| 09-May-2018 | UAE; 18BR003635; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Month(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 09-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment was treated with FRONTLINE PLUS (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 May 2018 - chosen at random), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . This is the extent of the information available. UPDATE 11 MAY 2018 - The pet owner was contacted and reported that Leopoldo, a male small crossbred dog of 10 months old and 4 kg, was treated with one vial of FRONTLINE PLUS DOG S (001/17, unknown exp date), topic, between the shoulder blades, applied by the reporter on 30 Apr 2018, for flea treatment. The environment has been treated with deltamethrin. It is unknown if FL has previously been applied. No further information is expected. |
| 10-May-2018 | UAE; 18BR003639; BA; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 10-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Leidy, a female mixed breed cat of 9 months old and 4 kg, was treated with FRONTLINE SPOT-ON CAT (FL) (lot and exp date are unknown, topical, neck and back - incorrect application), applied by the reporter around 1 week ago (3 May 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied . There is another cat in this household with the same issue (See case 18BR003640). No further information is expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 10-May-2018 | UAE; 18BR003640; BA; Brazil | **Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 10-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Aladin, a male Siamese of 6 years old and 6 kg, was treated with FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, neck and back - incorrect application), applied by the reporter around 1 week ago (3 May 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. There is another cat in this household with the same issue (See case 18BR003639). No further information is expected. |
| 09-May-2018 | UAE; 18BR003642; RJ; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 09-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lino, 12 years old, 7 kilogram, canine, male, Mixed Breed, received FRONTLINE SPOT-ON DOGS S (FL) (lot 004/17 and exp date Dec 2018, topically , between the shoulder blades), applied by the owner on 24 Apr 2018, for tick treatment. The owner complained about the lack of efficacy of FL because she continues to see ticks in her animal. According to the owner, she applied FL as soon as she noticed ticks in her animal and until now none was killed. The environment has been treated with TRYATOX®. There is another dog in the same household with similar problem (see case 18BR003643). It is unknown if the animal already received FL in the past. No further information is available. |
| 09-May-2018 | UAE; 18BR003643; RJ; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 09-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Ariel, 2 years old, 2.5 kilogram, canine, female, Yorkshire, received FRONTLINE SPOT-ON DOGS S (FL) (lot 004/17 and exp date Dec 2018, topically, between the shoulder blades ), applied by the owner on 24 Apr 2018, for tick treatment. The owner complained about the lack of efficacy of FL because she continues to see ticks in her animal. According to the owner, she applied FL as soon as she noticed ticks in her animal and until now none was killed. The environment has been treated with TRYATOX®. There is another dog in the same household with similar problem (see case 18BR003642). It is unknown if the animal already received FL in the past. Ariel also received BRAVECTO® in an unspecified date. No further information is available. |
| 10-May-2018 | UAE; 18BR003644; BA; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 30.00 Month(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 10-May-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner: Lola, 30 months old, 5 kilogram, canine, female, Yorkshire, received FRONTLINE SPRAY 100 mL (FL) (lot and exp date unknown, topically , sprayed on the animal´s hair), applied by the owner on 7 May 2018, for flea treatment. The owner complained about the lack of efficacy of FL because she did not see any effect . According to the owner, she applied FRONTLINE SPOT-ON® 2 months ago and when the fleas returned, she used FL but it has no effect. The environment has been treated with BUTOX®. There is also another dog in the same household with similar problem (see case 18BR003645). There is a suspected lack of efficacy of FRONTLINE SPOT-ON since it act controlling new infestations until 3 months post application (see cases 18BR003646 and 18BR003647). It is unknown if FL SPRAY has been used in the past. No further information is available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 10-May-2018 | UAE; 18BR003645; BA; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 56.00 Month(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 10-May-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Jhony, 56 months old, 4.5 kilogram, canine, male, Yorkshire, received FRONTLINE SPRAY 100 mL (FL) (lot and exp date unknown, topically, sprayed on the animal´s hair), applied by the owner on 7 May 2018, for flea treatment. The owner complained about the lack of efficacy of FL because she did not see any effect. According to the owner, she applied FRONTLINE SPOT-ON® 2 months ago and when the fleas returned, she used FL but it has no effect. The environment has been treated with BUTOX®. There is also another dog in the same household with similar problem (see case 18BR003644). There is a suspected lack of efficacy of FRONTLINE SPOT-ON since it act controlling new infestations until 3 months post application (see cases 18BR003646 and 18BR003647). It is unknown if FL SPRAY has been used in the past. No further information is available. |
| 10-May-2018 | UAE; 18BR003646; BA; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 30.00 Month(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 10-May-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lola, 30 months old, 5 kilogram, canine, female, Yorkshire, received FRONTLINE SPOT-ON® (FL) (lot, exp date, route and site of administration unknown), applied by the owner 2 months ago (10 Mar 2018 – estimated date), for unknown reason. According to the owner, 2 months after application, her animal got fleas. The environment has been treated with BUTOX®. There is another dog in the same household with a similar condition (see case 18BR003647). The owner also complained about the lack of efficacy of FRONTLINE SPRAY 100 mL (see cases 18BR003644 and 18BR003645). It is unknown if FL has been used before. No further information is available. |
| 10-May-2018 | UAE; 18BR003647; BA; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 56.00 Month(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 10-May-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Jhony, 56 months old, 4.5 kilogram, canine, male, Yorkshire, received FRONTLINE SPOT-ON® (FL) (lot, exp date, route and site of administration unknown), applied by the owner 2 months ago (10 Mar 2018 – estimated date), for unknown reason. According to the owner, 2 months after application, her animal got fleas. The environment has been treated with BUTOX®. There is another dog in the same household with a similar condition (see case 18BR003646) . The owner also complained about the lack of efficacy of FRONTLINE SPRAY 100 mL (see cases 18BR003644 and 18BR003645). It is unknown if FL has been used before. No further information is available. |
| 11-May-2018 | UAE; 18BR003656; ES; Brazil | **Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Unknown **Age:** 17.00 Month(s) **Weight:** 31 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 08-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a 17-month-old, 31 kg, female, Pit Bull, was treated with one vial of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp unknown), topic, between the shoulder blades, by the reporter, on 7 May 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation prior to FL, environment not treated, outdoor access. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 10-May-2018 | UAE; 18BR003657; -; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | N/A | 10-May-2018* | 5 Week(s) 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment received FRONTLINE PLUS (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Apr 2018 - chosen at random), for flea treatment. Lack of efficacy is |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | **Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | suspected because the pet remains with fleas. In addition, it is scratching itself due to fleas. This is the extent of the information available. |
| 10-May-2018 | UAE; 18BR003659; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 10-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, more than one cat of unknown signalment received FRONTLINE 'pipette' (unsubstantiated) (lot and exp unknown), by the reporter, 'yesterday' (9 May 2018), for flea treatment. Lack of efficacy suspected because the cats continued to have fleas . This is the extent of the information available. UPDATE 11 MAY 2018 - According to the owner, Chocolate, a male mixed breed cat of 2 years old and 2.5 kg, received one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 9 May 2018, for flea treatment. The environment has not been treated and it is unknown if FL has previously been applied. Similar cases reported on 18BR003666, 18BR003667, 18BR003668, 18BR003669, 18BR003670 and 18BR003671. No further information is expected. |
| 11-May-2018 | UAE; 18BR003661; MG; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Year(s)<br>**Weight:** 1.4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 11-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Yorkshire of 12 years old and and 1.4 kg, was treated with one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 4 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 10-May-2018 | UAE; 18BR003666; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 10-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Xudo, a male mixed breed cat of 7 years old and 4 kg, received one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 9 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. Similar cases were reported on 18BR003659, 18BR003667, 18BR003668, 18BR003669, 18BR003670 and 18BR003671. No further information is expected. |
| 10-May-2018 | UAE; 18BR003667; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | N/A | 10-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Preta, a female mixed breed cat of 7 years old and 4 kg, received one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 9 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. Similar cases were reported on 18BR003659, 18BR003666, 18BR003668, 18BR003669, 18BR003670 and 18BR003671. No further information is expected. |

N/A signifies the information for this field is either not available or not applicable

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Yes | | | | | |
| 10-May-2018 | UAE; 18BR003668; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female mixed breed cat of 7 years old and 4 kg, received one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 9 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. Similar cases were reported on 18BR003659, 18BR003666, 18BR003667, 18BR003669, 18BR003670 and 18BR003671. No further information is expected. |
| 10-May-2018 | UAE; 18BR003669; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Branca, a female mixed breed cat of 7 years old and 4 kg, received one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 9 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. Similar cases were reported on 18BR003659, 18BR003666, 18BR003667, 18BR003668, 18BR003670 and 18BR003671. No further information is expected. |
| 10-May-2018 | UAE; 18BR003670; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Princesa, a female mixed breed cat of 7 years old and 4 kg, received one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 9 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. Similar cases were reported on 18BR003659, 18BR003666, 18BR003667, 18BR003668, 18BR003669 and 18BR003671. No further information is expected. |
| 10-May-2018 | UAE; 18BR003671; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 10-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pantera, a female mixed breed cat of 7 years old and 6 kg, received one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 9 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. Similar cases were reported on 18BR003659, 18BR003666, 18BR003667, 18BR003668, 18BR003669 and 18BR003670. No further information is expected. |
| 11-May-2018 | UAE; 18BR003672; DF; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Pregnant Lactating **Age:** 15.00 Month(s) | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the** | N/A | 08-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one 7 kg, female dog (other signalment unknown), was treated with 1 x 100 ml bottle of FRONTLINE SPRAY (FL) (lot and exp unknown), by the reporter, on date not specified (1 May 2018 chosen at random), for flea treatment. All fleas died, however lack of efficacy was suspected because the dog is currently infested by fleas again. This is the extent of the information available. UPDATE 15 MAY 2018 - Luna, a 15-month-old, 10 kg, pregnant, crossbred dog, was treated with FL (004/17, Jan 2019), topic, |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 10 kg | | | | **product used ok?:** Yes | | | | | whole body, 2 weeks ago approximately (presumed 1 May 2018). Lack of efficacy was suspected because FL worked for only one week and Luna is infested by fleas again since then. Flea infestation 10 days prior to FL, environment treated once with Butox. It is unknown if FRONTLINE was applied to the dog in the past. There is no further information expected. |
| 11-May-2018 | UAE; 18BR003675; SP; Brazil | **Species:** Canine **Breed:** Chowchow **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 20 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 06-Jul-2017* | 11-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, an unidentified canine, male, Chow Chow received FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by an unidentified person, on an unspecified date (1 May 2018 – date chosen at random) for unknown reason. The owner complained about the lack of efficacy because he found ticks in his pet. The environmental conditions are unknown. The owner already used FL in the past (6 July 2017 – date chosen at random) with no issues. No further information is available. UPDATE 14 MAY 2018 - The pet owner was contacted and reported that, Laion, a male Chow Chow of approximately 3 years old and 20 kg, received one vial of FRONTLINE PLUS DOG M (FL) (topical, unknown location), applied by the reporter 2 weeks ago (30 Apr 2018 - estimated date), for tick treatment. The environment has not been treated. Bravecto® was administered recently and the pet is free of ticks. No further information is expected. |
| 14-May-2018 | UAE; 18BR003676; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 14-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the retail outlet staff member: an unidentified, 5 kilogram, canine, female, mixed breed, received 1 pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot 009/17, exp date, route and site of administration unknown), applied by the owner, on 4 May 2018, for flea treatment. The owner complained about the lack of efficacy because the dog remained with fleas. The environmental conditions are unknown. There is another dog in the same household with similar problem (see case 18BR003677). It is unknown if the animal already received FL in the past. No further information is available. |
| 14-May-2018 | UAE; 18BR003677; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 14-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the retail outlet staff member: an unidentified, 8 kilogram, canine, female, mixed breed, received 1 pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot 009/17, exp date, route and site of administration unknown), applied by the owner, on 4 May 2018, for flea treatment. The owner complained about the lack of efficacy because the dog remained with fleas. The environmental conditions are unknown. There is another dog in the same household with similar problem (see case 18BR003676). It is unknown if the animal already received FL in the past. No further information is available. |
| 14-May-2018 | UAE; 18BR003680; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | 01-Jan-2017* | 14-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a female small crossbreed dog of 11 years old and 5 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 4 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . In addition, the pet is scratching due to fleas. The environment has been treated with deltamethrin and FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). There is another dog in |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **ok?:** Yes | | | | | this household with the same issue (see case 18BR003681). No further information is expected. |
| 14-May-2018 | UAE; 18BR003681; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 14-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lola, a female small crossbreed dog of 7 years old and 8 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 4 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, the pet is scratching due to fleas. The environment has been treated with deltamethrin and FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). There is another dog in this household with the same issue (see case 18BR003680). No further information is expected. |
| 14-May-2018 | UAE; 18BR003682; -; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 14-May-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the retail outlet, one dog of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 11 May 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. This is the extent of the information available. |
| 14-May-2018 | UAE; 18BR003683; SP; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 29-Apr-2014* | 14-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Tunico, 5 years old, 7 kilogram, canine, male, Lhasa Apso received FRONTLINE SPRAY 250 mL (FL) (lot 009/16 and exp date JUN 2018, route and site of administration unknown), applied by the owner 15 days ago (29 Apr 2018 – estimated date), for flea and tick treatment. The owner complained about the lack of efficacy because FL is not having any effect. The environment has not been treated. The animal already received FL in the past and had no issues (29 Apr 2014 – date chosen at random). No further information is available. |
| 14-May-2018 | UAE; 18BR003689; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 13-Apr-2018 | 13-Apr-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lola, a 3-year-old, 4.5 kg, female, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (003/17, exp unknown), topic, some parts of the body, by the reporter, on 13 Apr 2018 and 11 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 3 months prior to FL, environment treated with K-Othrine. 3 other cats of the same household that are also on FL were reported on 18BR003690, 18BR003691 and 18BR003692. No further information is available. |
| 14-May-2018 | UAE; 18BR003690; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY | 13-Apr-2018 | 13-Apr-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Russo, a 2-year-old, 4 kg, male, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (003/17, exp unknown), topic, some |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 4 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | parts of the body, by the reporter, on 13 Apr 2018 and 11 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 3 months prior to FL, environment treated with K-Othrine. 3 other cats of the same household that are also on FL were reported on 18BR003689, 18BR003691 and 18BR003692. No further information is available. |
| 14-May-2018 | UAE; 18BR003691; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 5.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 13-Apr-2018 | 13-Apr-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bak, a 7-year-old, 5.5 kg, male, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (003/17, exp unknown), topic, some parts of the body, by the reporter, on 13 Apr 2018 and 11 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 3 months prior to FL, environment treated with K-Othrine. 3 other cats of the same household that are also on FL were reported on 18BR003689, 18BR003690 and 18BR003692. No further information is available. |
| 14-May-2018 | UAE; 18BR003692; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 13-Apr-2018 | 13-Apr-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Steven, an 8-year-old, 5 kg, male, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (003/17, exp unknown), topic, some parts of the body, by the reporter, on 13 Apr 2018 and 11 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 3 months prior to FL, environment treated with K-Othrine. 3 other cats of the same household that are also on FL were reported on 18BR003689, 18BR003690 and 18BR003691. No further information is available. |
| 14-May-2018 | UAE; 18BR003694; SP; Brazil | **Species:** Canine<br>**Breed:** Pinscher (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not | 23-Apr-2018 | 14-May-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bolinha, a female Pinscher of 1 year old and 2 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, back – incorrect application), applied by the reporter on 10 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product. FL was applied for the first time on 23 Apr 2018. Similar cases reported on 18BR003695, 18BR003696, 18BR003697 and 18BR003698. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | respected) | | | | | |
| 14-May-2018 | UAE; 18BR003695; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 23-Apr-2018 | 14-May-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Canelinha, a female medium crossbred dog of 5 years old and 14 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, back – incorrect application), applied by the reporter on 10 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product. FL was applied for the first time on 23 Apr 2018. Similar cases reported on 18BR003694, 18BR003696, 18BR003697 and 18BR003698. No further information is expected. |
| 14-May-2018 | UAE; 18BR003696; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 23-Apr-2018 | 14-May-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Teteka, a female small crossbred dog of 12 years old and 6 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, back – incorrect application), applied by the reporter on 10 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product. FL was applied for the first time on 23 Apr 2018. Similar cases reported on 18BR003694, 18BR003695, 18BR003697 and 18BR003698. No further information is expected. |
| 14-May-2018 | UAE; 18BR003697; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 23-Apr-2018 | 14-May-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Neguinha, a female small crossbred dog of 9 years old and 8 kg, was treated, for the second time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, back – incorrect application), applied by the reporter on 10 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product. FL was applied for the first time on 23 Apr 2018. Similar cases reported on 18BR003694, 18BR003695, 18BR003696 and 18BR003698. No further information is expected. |
| 14-May-2018 | UAE; 18BR003698; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 25.00 Day(s) **Weight:** 1 kg | 3 | 3 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the** | 23-Apr-2018 | 14-May-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 female crossbred dog puppies of 25 days old and around 1 kg, were treated, for the second time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, back – incorrect application), applied by the reporter on 10 May 2018, for flea treatment. Lack of efficacy is suspected because the pets remain with fleas. The environment has been treated with an unknown product. FL was applied for the first time on 23 Apr 2018. Similar cases reported on 18BR003694, 18BR003695, 18BR003696 and |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **product used ok?:** No (Treatment / vaccination program not respected) | | | | | 18BR003697. No further information is expected. |
| 05-May-2018 | UAE; 18BR003699; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 15-Mar-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Mel, 3 years old, 6 kilogram, canine, female, Mixed Breed, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot, and exp date unknown, topically, between the shoulder blades), administered by the owner 2 months ago (14 Mar 2018 – estimated date) for tick treatment. The owner complained that she continues to see ticks in her dog. According to the owner, animal already had ticks 2 weeks prior to treatment. The owner said that FL is used accordingly to the need approximately, every 3 months. The environment has been treated with BUTOX®. There are another 2 dogs in the same household with similar problem (see cases 18BR003534 and 18BR003700). No fleas were reported. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). No further information is available. |
| 14-May-2018 | UAE; 18BR003700; SP; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 14-May-2018* | 8 Week(s) 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Cherry, 12 years old, 3 kilogram, canine, female, Poodle, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot, and exp date unknown, topically, between the shoulder blades), administered by the owner 1 month ago (14 Apr 2018 – estimated date) for tick treatment. The owner complained that she continues to see ticks in her dog. According to the owner, animal already had ticks 2 weeks prior to treatment. The owner said that FL is used accordingly to the need approximately, every 3 months. The environment has been treated with BUTOX®. There are another 2 dogs in the same household with similar problem (see cases 18BR003534 and 18BR003699). No fleas were reported. FL was applied in the past with no issue (first application was not provided - 1 Jan 2017 chosen at random). No further information is available. |
| 11-May-2018 | UAE; 18BR003701; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jul-2016* | 13-Apr-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Curioso, a 2-year-old, 6 kg, male mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 32 days ago (12 Apr 2018) and 15 days ago approximately (presumed 29 Apr 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas . Flea infestation 2 days prior to FL, environment not treated. FRONTLINE was usually applied every 3 months with no issues (first dose on date not specified – 1 Jul 2016 chosen at random). No further information is available. |
| 14-May-2018 | UAE; 18BR003703; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other | N/A | 23-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Ana Banana, a 7-year-old, 4 kg, female mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, location unknown, by the reporter, on 22 Apr 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 3 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Age:** 7.00 Year(s)<br>**Weight:** 4 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | to the cat in the past. No further information is available. |
| 13-May-2018 | UAE; 18BR003704; -; Brazil | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 11.00 Month(s)<br>**Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 11-May-2018 | 13-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, Pipoca, a male Poodle of 11 months and 3.5 kg, received, for the first time, one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 11 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin once a week. No further information is expected. |
| 15-May-2018 | UAE; 18BR003708; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 12-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Taisson, 2 years old, 6 kilogram, canine, male, Shih Tzu, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot, and exp date unknown, topically, between the shoulder blades), administered by the owner on 5 May 2018, for flea treatment. The owner complained that FL did not work, the fleas did not die. According to the owner, animal already had fleas 1 weeks prior to treatment. The environment has been treated with BUTOX®. There are another 2 dogs in the same household with similar problem (see cases 18BR003709 and 18BR003710). The dog walks on the streets and the owner believes that is how the animal got fleas. It is unknown if the animal already received FL in the past. No further information is available. |
| 15-May-2018 | UAE; 18BR003709; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 12-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Tony, 3 years old, 6 kilogram, canine, male, Shih Tzu, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot, and exp date unknown, topically, between the shoulder blades), administered by the owner on 5 May 2018, for flea treatment. The owner complained that FL did not work, the fleas did not die. According to the owner, animal already had fleas 1 weeks prior to treatment. The environment has been treated with BUTOX®. There are another 2 dogs in the same household with similar problem (see cases 18BR003708 and 18BR003710). The dog walks on the streets and the owner believes that is how the animal got fleas. It is unknown if the animal already received FL in the past. No further information is available. |
| 15-May-2018 | UAE; 18BR003710; SP; Brazil | **Species:** Canine<br>**Breed:** Pinscher (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 11.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the** | N/A | 12-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Mel, 11 years old, 5 kilogram, canine, female, Pinscher, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot, and exp date unknown, topically, between the shoulder blades), administered by the owner on 5 May 2018, for flea treatment. The owner complained that FL did not work, the fleas did not die. According to the owner, animal already had fleas 1 weeks prior to treatment. The environment has been treated with BUTOX®. There are another 2 dogs in the same household with similar problem (see cases 18BR003708 and 18BR003709). The dog walks on the streets and the owner believes that is how the animal got fleas. It is |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **product used ok?:** Yes | | | | | unknown if the animal already received FL in the past. No further information is available. |
| 12-May-2018 | UAE; 18BR003712; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 12-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mamy, a female mixed breed cat of 6 years old and 5 kg, was treated with one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, neck - incorrect application), applied by the reporter on 11 May 2018, for flea treatment. The owner believes that FL is not working because it only lasts one month. No ectoparasite was reported. The environment has not been treated and FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases reported on 18BR003713 and 18BR003714. PQC case was also reported on 18BR003715. No further information is expected. |
| 12-May-2018 | UAE; 18BR003713; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 12-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nepreto, a female mixed breed cat of 5 years old and 5 kg, was treated with one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, neck - incorrect application), applied by the reporter on 11 May 2018, for flea treatment. The owner believes that FL is not working because it only lasts one month. No ectoparasite was reported. The environment has not been treated and FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases reported on 18BR003712 and 18BR003714. PQC case was also reported on 18BR003715. No further information is expected. |
| 12-May-2018 | UAE; 18BR003714; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 12-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lebranca, a female mixed breed cat of 5 years old and unknown weight, was treated with one vial of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, neck - incorrect application), applied by the reporter on 11 May 2018, for flea treatment. The owner believes that FL is not working because it only lasts one month. No ectoparasite was reported. The environment has not been treated and FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases reported on 18BR003712 and 18BR003713. PQC case was also reported on 18BR003715. No further information is expected. |
| 14-May-2018 | UAE; 18BR003721; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous | 01-Jan-2017* | 14-May-2018* | 4 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nero, a male medium crossbred dog of 5 years old and 12 kg, was treated with FRONTLINE DOG M (unsubstantiated) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 16 Apr 2018, for tick control. Lack of efficacy is suspected because the pet has live ticks. The environment has not been treated and FL has been applied every 3 months (first application was not provided - 1 Jan 2017 chosen at random). |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 12 kg | | | | **Was the product used ok?:** Yes | | | | | There is another dog in this household that was not treated with FL and it has no issue. No further information is expected. |
| 15-May-2018 | UAE; 18BR003724; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 13 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 15-Apr-2018* | 15-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bolinha, a male medium crossbred dog of 10 years old and 13 kg, was treated with FRONTLINE SPRAY (FL) (016/16, Nov 2018, topical, whole body), applied by the reporter around 30 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and FL was also applied one month ago and did not work (15 Apr 2018 - estimated date). Similar cases reported on 18BR003725, 18BR003726 and 18BR003727. No further information is expected. UPDATE 12 JUL 2018 - The owner continues to see fleas on her animal. FL has not been applied since the last application. No further information is expected. |
| 15-May-2018 | UAE; 18BR003725; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 12 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 15-Apr-2018* | 15-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pipoca, a male medium crossbred dog of 8 years old and 12 kg, was treated with FRONTLINE SPRAY (FL) (016/16, Nov 2018, topical, whole body), applied by the reporter around 30 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and FL was also applied one month ago and did not work (15 Apr 2018 - estimated date). Similar cases reported on 18BR003724, 18BR003726 and 18BR003727. No further information is expected. UPDATE 12 JUL 2018 - The owner continues to see fleas on her animal. FL has not been applied since the last application. No further information is expected. |
| 15-May-2018 | UAE; 18BR003726; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 15-Apr-2018* | 15-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nino, a male mixed breed cat of 8 years old and 7 kg, was treated with FRONTLINE SPRAY (FL) (016/16, Nov 2018, topical, whole body), applied by the reporter around 30 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and FL was also applied one month ago and did not work (15 Apr 2018 - estimated date). Similar cases reported on 18BR003724, 18BR003725 and 18BR003727. No further information is expected. UPDATE 12 JUL 2018 - The owner continues to see fleas on her animal. FL has not been applied since the last application. No further information is expected. |
| 15-May-2018 | UAE; 18BR003727; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / | 15-Apr-2018* | 15-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pucca, a female mixed breeds cat of 6 years old and 8 kg, was treated with FRONTLINE SPRAY (FL) (016/16, Nov 2018, topical, whole body), applied by the reporter around 30 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and FL was also applied one month ago and did not work (15 Apr |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Age:** 6.00 Year(s)<br>**Weight:** 8 kg | | | | Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | 2018 - estimated date). Similar cases reported on 18BR003724, 18BR003725 and 18BR003726. No further information is expected. UPDATE 12 JUL 2018 - The owner continues to see fleas on her animal. FL has not been applied since the last application. No further information is expected. |
| 15-May-2018 | UAE; 18BR003731; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 18-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Tuffi, a 6-year-old, 7 kg, male, Shih Tzu, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 17 Apr 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 2 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 14-May-2018 | UAE; 18BR003732; SP; Brazil | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Month(s)<br>**Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-May-2018* | 14-May-2018* | 13 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Aria, a female cat of 3 months old and 1.5 kg (breed unknown), received, for the first time, one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter two weeks ago (1 May 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. There is another cat in this household with the same issue (see case 18BR003733). No further information is expected. |
| 14-May-2018 | UAE; 18BR003733; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Month(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-May-2018* | 14-May-2018* | 13 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Airon, a male mixed breed cat of 5 months old and 2 kg, received, for the first time, one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter two weeks ago (1 May 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. There is another cat in this household with the same issue (see case 18BR003732). No further information is expected. |
| 15-May-2018 | UAE; 18BR003735; MG; Brazil | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Month(s) | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous | N/A | 15-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Marley, a male Labrador of 2 months old and 3.8 kg, was treated with FRONTLINE SPRAY (FL) (lot 003/17 and exp date is unknown, topical, location unknown), applied by the reporter 15 days ago (30 Apr 2018 - estimated date), for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with cypermethrin and it is unknown if FL has previously been applied. The dog has no outdoor access. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Weight:** 3.8 kg | | | | **Was the product used ok?:** Unknown to Company | | | | | No further information is expected. |
| 15-May-2018 | UAE; 18BR003736; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 17.00 Month(s) **Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 15-May-2018* | 11 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Amora, a female medium crossbred dog of 17 months old and 14 kg, received one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 4 May 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 16-May-2018 | UAE; 18BR003740; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 28-Apr-2018* | 16-May-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bili, a male Yorkshire Terrier of unknown age and 7 kg, received, for the second time, one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 12 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has not been treated and FL was applied for the first time in the end of April 2018 (28 Apr 2018 - estimated date), and did not work also. No further information is expected. |
| 16-May-2018 | UAE; 18BR003746; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-May-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Fally, a female mixed breed cat of 3 years old and 6 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 2 weeks ago (2 May 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has not been treated and it is unknown if FL has previously been applied. There is another cat in this household with the same issue (see case 18BR003747). No further information is expected. |
| 16-May-2018 | UAE; 18BR003747; SP; Brazil | **Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | N/A | 16-May-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lilica, a female Siamese of 15 years old and 3.5 kg, received one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 2 weeks ago (2 May 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has not been treated and it is unknown if FL has previously been applied. There is another cat in this household with the same issue (see case 18BR003746). No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Yes | | | | | |
| 16-May-2018 | UAE; 18BR003749; PR; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 1.3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-May-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Shakira, 3 months old, 1.3 kilogram, canine, female, Yorkshire, received 1 pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner, on 7 May 2018, for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her animal. According to the owner, animal already had fleas 1 week prior to treatment. The environment has not been treated. It is unknown if the animal received FL in the past. No further information is available. |
| 16-May-2018 | UAE; 18BR003754; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Jimmy, a 5-year-old, 4 kg, male mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (007/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 15 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation prior to FL, environment treated. It is unknown if FRONTLINE was applied to the cat in the past. There are one other cat and one dog in the same household that were treated with other company's product, and are not infested by fleas. No further information is available. |
| 15-May-2018 | UAE; 18BR003755; SP; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 22 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 30-Jul-2017* | 15-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Kiara, 1 year old, 22 kilogram, canine, female, Mixed Breed, received 1 pipette of FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner, on 30 Apr 2018, for tick treatment. The owner complained about the lack of efficacy because she continues to see ticks in her animal. According to the owner, animal already had ticks 3 months prior to treatment. The environment has been treated with BUTOX®. The owner used FL for years but It was the third time the product has failed to treat ticks (first use on 30 Jul 2017 – date chosen at random). The other 2 failures were not specified. There is also another dog in the same household with similar problem ( see case 18BR003756). No further information is available. |
| 15-May-2018 | UAE; 18BR003756; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 20 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 30-Apr-2013* | 15-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Nina, 6 year old, 20 kilogram, canine, female, Mixed Breed, received 1 pipette of FRONTLINE PLUS DOG M (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner, on 30 Apr 2018, for tick treatment. The owner complained about the lack of efficacy because she continues to see ticks in her animal. According to the owner, animal already had ticks 3 months prior to treatment. The environment has been treated with BUTOX®. The owner used FL for years but It was the third time the product has failed to treat ticks (first use on 30 Apr 2013 – date chosen at random). The other 2 failures were not specified. There is also another dog in the same household with similar problem (see case 18BR003755). No further information is available. |
| 15-May-2018 | UAE; 18BR003761; | **Species:** Canine **Breed:** Chowchow | 1 | 1 | 0 | **Product used:** FIPRONIL | 01-Jan-2017* | 15-May-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Boquinha, a male Chow Chow of 8 years old and 27 kg, |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | PE; Brazil | **Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 27 kg | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | received one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, neck and back - incorrect application), applied by the reporter on 9 May 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with an unknown product and FL has been applied every 3 months (first application was not provided - 1 Jan 2017 chosen at random). There is another dog in this household with the same issue (see case 18BR003762). No further information is expected. |
| 15-May-2018 | UAE; 18BR003762; PE; Brazil | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 38 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 15-May-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Mel, a female Labrador of 8 years old and 38 kg, received one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, neck and back - incorrect application), applied by the reporter on 9 May 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with an unknown product and FL has been applied every 3 months (first application was not provided - 1 Jan 2017 chosen at random). There is another dog in this household with the same issue (see case 18BR003761). No further information is expected. |
| 15-May-2018 | UAE; 18BR003763; SC; Brazil | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 13.00 Year(s)<br>**Weight:** 11 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 15-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Tobias, a male Poodle of 13 years old and 11 kg, received one vial of FRONTLINE SPOT-ON DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 16 days ago (30 Apr 2018 - estimated date), for tick treatment. Lack of efficacy is suspected because the pet has ticks. The environment has not been treated. FL has been applied every 3 months (first application was not provided - 1 Jan 2017 chosen at random). There is another dog in this household with the same issue (see case 18BR003764). No further information is expected. |
| 15-May-2018 | UAE; 18BR003764; SC; Brazil | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 10.00 Year(s)<br>**Weight:** 8.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 15-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Billy, a male Poodle of 10 years old and 8.5 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 16 days ago (30 Apr 2018 - estimated date), for tick treatment. Lack of efficacy is suspected because the pet has ticks. The environment has not been treated. FL has been applied every 3 months (first application was not provided - 1 Jan 2017 chosen at random). There is another dog in this household with the same issue (see case 18BR003763). No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 16-May-2018 | UAE; 18BR003766; RJ; Brazil | **Species:** Canine **Breed:** Pug **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 14-May-2018* | 14-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Ramon, 2 months old, 3 kilogram, canine, male, Pug, received FRONTLINE SPRAY (FL) (lot 017/16 and exp date unknown, topically, in the whole body), applied by the owner, on Monday (14 May 2018 – estimated date) and today (16 May 2018), for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her animal. According to the owner, animal already had fleas 15 days prior to treatment. The environment has not been treated. No further information is available. |
| 17-May-2018 | UAE; 18BR003774; SC; Brazil | **Species:** Canine **Breed:** Pug **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-May-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Meg, a female Pug of unknown age and 8 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 12 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied . Similar cases reported on 18BR003775 and 18BR003776. No further information is expected. |
| 17-May-2018 | UAE; 18BR003775; SC; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-May-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pitita, a female small crossbred dog of unknown age and 5 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 12 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. Similar cases reported on 18BR003774 and 18BR003776. No further information is expected. |
| 17-May-2018 | UAE; 18BR003776; SC; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-May-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lili, a female medium crossbred dog of 3 years old and 10 kg, received one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 12 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. Similar cases reported on 18BR003774 and 18BR003775. No further information is expected. |
| 14-May-2018 | UAE; 18BR003777; RS; Brazil | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON | 01-Jul-2008* | 15-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one 10-year-old cat (other signalment unknown) was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), by the reporter, 30 days ago approximately (presumed 14 Apr 2018), for flea treatment. Lack of efficacy suspected |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** Unknown | | | | **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | | | | | because the cat continued to have fleas. FRONTLINE was applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jul 2008 chosen at random). Outdoor access and contact with untreated animals denied. One dog of the same household that is also on FRONTLINE was reported on 18BR003778. No further information is available. |
| 14-May-2018 | UAE; 18BR003778; RS; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Jan-2017* | 15-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment was treated with one vial of FRONTLINE PLUS DOGS (size, lot and exp unknown), by the reporter, 30 days ago approximately (presumed 14 Apr 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. FRONTLINE was applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2017 chosen at random). Outdoor access and contact with untreated animals denied. One cat of the same household that is also on FRONTLINE was reported on 18BR003777. No further information is available. |
| 14-May-2018 | UAE; 18BR003779; SP; Brazil | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 4 | 4 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 12-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 4 female cats of unknown signalment were treated with 1 vial each of FRONTLINE PLUS CATS (FL) (lot and exp unknown), by the reporter, near 11 May 2018, for flea treatment. Lack of efficacy suspected because the cats continued to have fleas. This is the extent of the information available. |
| 17-May-2018 | UAE; 18BR003784; PR; Brazil | **Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 34 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 03-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a 5-year-old, 34 kg, female, Pit Bull, was treated with one vial of FRONTLINE SPOT-ON DOGS L (FL), topic, base of skull and btw the shoulder blades, by the retail store staff, on 2 May 2018, for flea and tick treatment. Lack of efficacy suspected because the dog continued to have fleas and ticks. Flea and tick infestation one day prior to FL, environment treated. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FRONTLINE was reported on 18BR003785. No further information is available. |
| 17-May-2018 | UAE; 18BR003785; PR; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 2.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | N/A | 03-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bolota, a 4-month-old, 2.6 kg, male, Shih Tzu, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL), topic, base of skull and btw the shoulder blades, by the retail store staff, on 2 May 2018, for flea and tick treatment. Lack of efficacy suspected because the dog continued to have fleas and ticks. Flea and tick infestation one day prior to FL, environment treated. It is unknown if FRONTLINE was applied to the dog in the past. One other dog of the same household that is also on FRONTLINE was reported on 18BR003784. No further information is available. |

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| | | | | | | **ok?:** Yes | | | | | |
| 16-May-2018 | UAE; 18BR003793; SP; Brazil | **Species:** Canine **Breed:** French Bulldog **Sex:** F **Sex qualifier:** Unknown **Age:** 4.50 Year(s) **Weight:** 16 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jul-2017* | 15-Jan-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: AS reported by the pet owner, Judth, a female French Bulldog of 4.5 years old and 16 kg, was treated with one vial of FROTNLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, neck and btw the shoulder blades - incorrect application), applied by the reporter on Jan 2018 (1 Jan 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product. FL has been applied in the past with the same issue (dose frequency is unknown; first application was not provided - 1 Jul 2017 - chosen at random). Similar cases reported on 18BR003794 and 18BR003795. No further information is expected. |
| 16-May-2018 | UAE; 18BR003794; SP; Brazil | **Species:** Canine **Breed:** French Bulldog **Sex:** M **Sex qualifier:** Unknown **Age:** 2.50 Year(s) **Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jul-2017* | 15-Jan-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: AS reported by the pet owner, Didjalma, a male French Bulldog of 2.5 years old and 14 kg, was treated with one vial of FROTNLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, neck and btw the shoulder blades - incorrect application), applied by the reporter on Jan 2018 (1 Jan 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product. FL has been applied in the past with the same issue (dose frequency is unknown; first application was not provided - 1 Jul 2017 - chosen at random). Similar cases reported on 18BR003793 and 18BR003795. No further information is expected. |
| 16-May-2018 | UAE; 18BR003795; SP; Brazil | **Species:** Canine **Breed:** French Bulldog **Sex:** M **Sex qualifier:** Unknown **Age:** 2.50 Year(s) **Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jul-2017* | 15-Jan-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: AS reported by the pet owner, Pepe, a male French Bulldog of 2.5 years old and 14 kg, was treated with one vial of FROTNLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, neck and btw the shoulder blades - incorrect application), applied by the reporter on Jan 2018 (1 Jan 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product. FL has been applied in the past with the same issue (dose frequency is unknown; first application was not provided - 1 Jul 2017 - chosen at random). Similar cases reported on 18BR003793 and 18BR003794. No further information is expected. |
| 16-May-2018 | UAE; 18BR003796; MG; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG | 26-Apr-2018 | 06-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Chop, a male Shih Tzu of 3 months old (born on 8 Jan 2018) and 3 kg, was treated, for the first time, with one vial of |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 3 kg | | | | **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 26 Apr 2018, for tick treatment. Lack of efficacy is suspected because the pet had ticks. The environment was fumigated on 3 May 2018 and two ticks were found on his dog. So, she applied FRONTLINE SPRAY on 16 May 2018. The current status of the animal is unknown. No further information is available. UPDATE 18 MAY 2018 – According to the owner, Chop has 4 months old. The current status of the animal is unknown. No further information is available. |
| 17-May-2018 | UAE; 18BR003799; SP; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 14-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Paçoca, a 4-year-old, 9 kg, male, Lhasa Apso, was treated with one vial of FRONTLINE PLUS DOG S (FL) (023/17, Jun 2019), topic, location unknown, by the reporter, on 13 May 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 5 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 16-May-2018 | UAE; 18BR003800; RJ; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 12-May-2018 | 12-May-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one female Yorkshire Terrier (other signalment unknown) was treated with FRONTLINE (unsubstantiated) (lot and exp unknown), by the reporter, for the first time, on 12 May 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. The dog was usually treated with other company's product with no issues. This is the extent of the information available. |
| 18-May-2018 | UAE; 18BR003804; SP; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 48 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | N/A | 18-May-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lili, a female dog of approximately 3 years old and 48 kg and unknown breed, was treated with one vial of FRONTLINE PLUS DOG L (FL) (006/17 and unknown exp date, topical, unknown location), applied by the reporter on 9 May 2018, for flea treatment. Flea infestation 2 months prior to FL. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 17-May-2018 | UAE; 18BR003810; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products** | 15-Jan-2018* | 17-May-2018 | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: an unidentified dog, received 1 pipette of an unidentified FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by the owner, on an unspecified date (15 May 2018 – date chosen at random), for flea and tick treatment. The owner complained about the lack of efficacy because according to |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Month(s)<br>**Weight:** 4.5 kg | | | | **used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | him the product had no effect. According to the owner, he already had use FRONTLINE® and FRONTLINE SPRAY together, in the past (15 May 2015 - date chosen at random), with no issues. The owner also complained about the lack of efficacy of FRONTLINE SPRAY (see case 18BR003811). The product was applied according to label. No further information is available. UPDATE 21 MAY 2018 – The dog is Chubaca, a 14 months old, 4.5 kilogram, canine, female, Shih Tzu. In the new contact made with the owner, no issue was reported regarding a pipette this time. According to the owner, he already used in the past (15 Jan 2018 - date chosen at random). No further information is available. |
| 17-May-2018 | UAE; 18BR003811; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 14.00 Month(s)<br>**Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 15-Jan-2018* | 17-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: an unidentified dog, received a dose of FRONTLINE SPRAY (FL) (lot, exp date, route and site of administration unknown), applied by the owner, on an unspecified date (15 May 2018 – date chosen at random), for flea and tick treatment. The owner complained about the lack of efficacy because according to him the product had no effect. According to the owner, he already had use FRONTLINE® and FRONTLINE SPRAY together, in the past (15 May 2015 - date chosen at random), with no issues. The owner also complained about the lack of efficacy of FRONTLINE® (see case 18BR003810). The product was applied according to label. No further information is available. UPDATE 21 MAY 2018 – The dog is Chubaca, a 14 months old, 4.5 kilogram, canine, female, Shih Tzu, received a dose of FL (lot 012/16, exp date Aug 2018, topically, whole body) According to the owner, animal already had fleas 1 day prior to treatment. The owner also have another 3 dogs, who were treated with a different product and stays in a different area from the house. The environment has been treated with K-OTHRINE®. The owner also gave a chew of COMFORTIS® to Chubaca and according to him, the fleas number decreased. According to the owner, FL has been used in the past (15 Jan 2018 - date chosen at random)No further information is available. |
| 17-May-2018 | UAE; 18BR003815; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 05-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 3 female dogs of unknown signalment were treated with FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 May 2018 - chosen at random), for flea treatment. Lack of efficacy is suspected because the dogs remain with fleas. In addition, they have no contact with other animals. This is the extent of the information available. UPDATE 21 MAY 2018 – Luli, 6 years old, 3.5 kilogram, canine, female, Shih Tzu, received 1 pipette of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 4 Apr 2018. Flea infestation 2 days prior to FL, the dog only stays inside the house. The environment has been treated with an unidentified insecticide product. There are another 2 dogs in the same household with similar problem (see cases 18BR003849 and 18BR003850). It is unknown if FL was applied in the past. No further information is available. |
| 17-May-2018 | UAE; 18BR003816; -; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Unknown | 1 | 1 | 1 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other | N/A | 12-May-2018 | N/A | D-A | Suspected Adverse Event: Initially as reported by the owner via retail outlet:: Mel, age unknown, 3 to 5 kilogram,canine, female,Shih Tzu, received FRONTLINE SPRAY (FL) (lot 003/17 and exp date unknown, topically, applied in the neck), applied by the owner, on saturday (12 May 2018) around 6 p.m. and on |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Age:** -<br>**Weight:** 3 - 5 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | sunday (13 May 2018) around 2 p.m., for flea treatment. According to the owner, on saturday, the animal was taken to the pet shop to receive a bath and cut the hair, by that time, the animal was in a good health state. After the bath, the animal was returned home around 3 to 4 p.m. and during the meal time presented loss of appetite. On sunday the animal was apathetic and by monday presented vomiting, hypersalivation and diarrhea, initially without blood, but later on with blood in vomiting and diarrhea. On tuesday (15 May 2018) the animal presented an intense drooling and died around 11 a.m. Mel gave birth 30 days prior to the incident and her puppy also received FL and had a reaction (see case 18BR003817). It is unknown if the animal already received FL in the past. No further information is available. |
| 17-May-2018 | UAE; 18BR003817; -; Brazil | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Week(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 13-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: Initially as reported by the owner:: an unidentified male dog puppy, born in 5 Apr 2018, received FRONTLINE SPRAY (FL) (lot 003/17 and exp date unknown, topically, applied in the neck), applied by the owner, on saturday (12 May 2018) around 6 p.m. and on sunday (13 May 2018) around 2 p.m., for flea treatment. According to the owner, the animal start to present, on an unidentified date (13 May 2018 – date chosen at random), a 'strong' breath as if he was with bronchitis (irregular breathing), the animal also presented weakness, can´t stand for too long, he takes a few steps and then lie on the floor. The animal was taken to the veterinary, was medicated and hospitalized. According to the owner, the DVM said it was an intoxication. The animal health conditions are unknown. There is also another similar case, regarding the puppy´s mother (see case 18BR003816). It is unknown if the animal already received FL in the past. No further information is available. |
| 18-May-2018 | UAE; 18BR003820; RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Month(s)<br>**Weight:** 1.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2018* | 04-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Simba, a 7-month-old, 1.7 kg, male, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. As FL did not work, the product was applied again one week ago (11 May 2018), but Simba is still infested by fleas. Flea infestation prior to FL, environment treated. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003821 to 18BR003828. SAE case reported on 18BR003829. No further information is available. |
| 18-May-2018 | UAE; 18BR003821; RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Month(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / | 01-Jan-2018* | 04-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Stuart, a 7-month-old, 2 kg, male, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. As FL did not work, the product was applied again one week ago (11 May 2018), but Stuart is still infested by fleas. Flea infestation prior to FL, environment treated. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported on 18BR003820 and from 18BR003822 to 18BR003828. SAE case reported on |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | vaccination program not respected) | | | | | 18BR003830. No further information is available. |
| 18-May-2018 | UAE; 18BR003822; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 75.00 Day(s) **Weight:** 1.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Apr-2018* | 04-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Seven, a 75-day-old, 1.1 kg, male, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. As FL did not work, the product was applied again one week ago (11 May 2018), but Seven is still infested by fleas. Flea infestation prior to FL, environment treated. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Apr 2018 chosen at random). Similar cases reported on 18BR003820, 18BR003821 and from 18BR003823 to 18BR003828. SAE case reported on 18BR003831. No further information is available. |
| 18-May-2018 | UAE; 18BR003823; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2018* | 04-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sapatin, a 7-month-old, 1 kg, male, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. As FL did not work, the product was applied again one week ago (11 May 2018), but Sapatin is still infested by fleas. Flea infestation prior to FL, environment treated. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003820 to 18BR003822, and from 18BR003824 to 18BR003828. SAE case reported on 18BR003832. No further information is available. |
| 18-May-2018 | UAE; 18BR003824; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2018* | 04-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Piti, a 7-year-old, 15 kg, male, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas . As FL did not work, the product was applied again one week ago (11 May 2018), but Piti is still infested by fleas. Flea infestation prior to FL, environment treated. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003820 to 18BR003823, and from 18BR003825 to 18BR003828. SAE case reported on 18BR003833. No further information is available. |
| 18-May-2018 | UAE; 18BR003825; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / | 01-Jan-2018* | 04-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bobi, a 7-year-old, 11 kg, female, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. As FL did not work, the product was applied again one week ago (11 May 2018), but Bobi is still infested by fleas. Flea |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Age:** 7.00 Year(s)<br>**Weight:** 11 kg | | | | Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | infestation prior to FL, environment treated. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003820 to 18BR003824, and from 18BR003826 to 18BR003828. SAE case reported on 18BR003834. No further information is available. |
| 18-May-2018 | UAE; 18BR003826; RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2018* | 04-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Chana, a 6-year-old, 4 kg, female, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. As FL did not work, the product was applied again one week ago (11 May 2018), but Chana is still infested by fleas. Flea infestation prior to FL, environment treated. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003820 to 18BR003825, 18BR003827 and 18BR003828. SAE case reported on 18BR003835. No further information is available. |
| 18-May-2018 | UAE; 18BR003827; RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 19.00 Month(s)<br>**Weight:** 1.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2018* | 04-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, SKP, a 19-month-old, 1.8 kg, female, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. As FL did not work, the product was applied again one week ago (11 May 2018), but SKP is still infested by fleas. Flea infestation prior to FL, environment treated. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003820 to 18BR003826 and 18BR003828. SAE case reported on 18BR003836. No further information is available. |
| 18-May-2018 | UAE; 18BR003828; RJ; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 12 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2018* | 04-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pak, a 5-year-old, 12 kg, female, crossbred dog, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. As FL did not work, the product was applied again one week ago (11 May 2018), but Pak is still infested by fleas. Flea infestation prior to FL, environment treated. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003820 to 18BR003827. SAE case reported on 18BR003837. No further information is available. |
| 18-May-2018 | UAE; 18BR003829; | **Species:** Feline<br>**Breed:** Feline | 1 | 1 | 0 | **Product used:** FIPRONIL | 01-Jan-2018* | 04-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Simba, a 7-month-old, 1.7 kg, male, mixed breed cat, was treated with |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | RJ; Brazil | mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Month(s)<br>**Weight:** 1.7 kg | | | | SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Few minutes following product application, the cat started experiencing sneezing and lacrimation. Simba recovered on date not specified. Since FL did not work (SLOE case reported on 18BR003820), the product was applied again one week ago ( 11 May 2018), however there is no information regarding symptoms post this new dose of FL. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003830 to 18BR003837. There is no further information expected. |
| 18-May-2018 | UAE; 18BR003830; RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Month(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2018* | 04-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Stuart, a 7-month-old, 2 kg, male, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Few minutes following product application, the cat started experiencing sneezing and lacrimation. The signs are still ongoing. Since FL did not work (SLOE case reported on 18BR003821), the product was applied again one week ago ( 11 May 2018). FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported on 18BR003829 and from 18BR003831 to 18BR003837. There is no further information expected. |
| 18-May-2018 | UAE; 18BR003831; RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 75.00 Day(s)<br>**Weight:** 1.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Apr-2018* | 04-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Seven, a 75-day-old, 1.1 kg, male, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Few minutes following product application, the cat started experiencing sneezing and lacrimation. Seven recovered on date not specified. Since FL did not work (SLOE case reported on 18BR003822), the product was applied again one week ago ( 11 May 2018), however there is no information regarding symptoms post this new dose of FL. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported on 18BR003829 and 18BR003830, and from 18BR003832 to 18BR003837. There is no further information expected. |
| 18-May-2018 | UAE; 18BR003832; RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Month(s)<br>**Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination | 01-Jan-2018* | 04-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Sapatin, a 7-month-old, 1 kg, male, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Few minutes following product application, the cat started experiencing sneezing and lacrimation. Sapatin recovered on date not specified. Since FL did not work (SLOE case reported on 18BR003823), the product was applied again one week ago ( 11 May 2018), however there is no information regarding symptoms post this new dose of FL. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003829 to 18BR003831, and from 18BR003833 to |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | program not respected) | | | | | 18BR003837. There is no further information expected. |
| 18-May-2018 | UAE; 18BR003833; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2018* | 04-May-2018 | N/A | D-D | Suspected Adverse Event: As reported by the pet owner, Piti, a 7-year-old, 15 kg, male, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Few minutes following product application, the cat started experiencing sneezing and lacrimation. The signs are still ongoing. Since FL did not work (SLOE case reported on 18BR003824), the product was applied again one week ago (11 May 2018). FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003829 to 18BR003832, and from 18BR003834 to 18BR003837. There is no further information expected. |
| 18-May-2018 | UAE; 18BR003834; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 11 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2018* | 04-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Bobi, a 7-year-old, 11 kg, female, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Few minutes following product application, the cat started experiencing sneezing and lacrimation. Bobi recovered on date not specified. Since FL did not work (SLOE case reported on 18BR003825), the product was applied again one week ago (11 May 2018), however there is no information regarding symptoms post this new dose of FL. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003829 to 18BR003833, and from 18BR003835 to 18BR003837. There is no further information expected. |
| 18-May-2018 | UAE; 18BR003835; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2018* | 04-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Chana, a 6-year-old, 4 kg, female, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Few minutes following product application, the cat started experiencing sneezing and lacrimation. Chana recovered on date not specified. Since FL did not work (SLOE case reported on 18BR003826), the product was applied again one week ago (11 May 2018), however there is no information regarding symptoms post this new dose of FL. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003829 to 18BR003834, 18BR003836 and 18BR003837. There is no further information expected. |
| 18-May-2018 | UAE; 18BR003836; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 19.00 | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous | 01-Jan-2018* | 04-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, SKP, a 19-month-old, 1.8 kg, female, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Few minutes following product application, the cat started experiencing sneezing and lacrimation. SKP recovered on date not specified. Since FL did not work (SLOE case reported on 18BR003827), the product was applied again one week ago (11 May 2018), however |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Month(s)<br>**Weight:** 1.8 kg | | | | **Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | there is no information regarding symptoms post this new dose of FL. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003829 to 18BR003835, and 18BR003837. There is no further information expected. |
| 18-May-2018 | UAE; 18BR003837; RJ; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 12 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2018* | 04-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Pak, a 5-year-old, 12 kg, female, crossbred dog, was treated with FRONTLINE SPRAY (FL) (005/16, May 2018), topic, base of skull, by the reporter, 2 weeks ago (4 May 2018), for flea treatment. Few minutes following product application, the dog started experiencing sneezing and lacrimation. Hair loss also mentioned. Pak recovered on date not specified. Since FL did not work (SLOE case reported on 18BR003828), the product was applied again one week ago ( 11 May 2018), however there is no information regarding symptoms post this new dose of FL. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2018 chosen at random). Similar cases reported from 18BR003829 to 18BR003836. There is no further information expected. |
| 18-May-2018 | UAE; 18BR003842; MG; Brazil | **Species:** Canine<br>**Breed:** Retriever (Golden)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 18.00 Month(s)<br>**Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jul-2017* | 18-May-2018* | 18 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female dog of 18 months old (other signalment is unknown) was treated with one vial of FRONTLINE 'pipette' (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 30 Apr 2018, for tick control. Lack of efficacy is suspected because the pet has ticks . FL has been applied every 3 months since date not specified (1 Jul 2017 – chosen at random). This is the extent of the information available. UPDATE 25 MAY 2018 - According to the owner, Luna, a female Golden Retriever of 18 months old and 35 kg, was treated with one vial of FRONTLINE SPOT-ON DOG L, topical, btw the shoulder blades, applied by the reporter on 30 Apr 2018. Live ticks still have been found on the pet. The environment has been treated with deltamethrin. No further information is expected. |
| 18-May-2018 | UAE; 18BR003843; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 4.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jul-2017* | 18-May-2018* | 17 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female cat of unknown signalment received FRONTLINE CATS (unsubstantiated) (FL) (011/17, Dec 2018, route and location are unknown), applied by the reporter on date not specified (1 May 2018 – chosen at random). The owner believes that FL is not working because his pet is scratching itself . No ectoparasites were reported. FL was applied in the past with no issue (1 Jul 2017 - chosen at random). No further information is available. UPDATE 22 MAY 2018 - The pet owner was contacted and reported that Sofia, a female mixed breed cat of 6 years old and 4.7 kg was treated with one vial of FRONTLINE SPOT-ON CATS. Because of itching, the pet was taken to the vet and was diagnosed with otitis. The pet has recovered. No further information is available. |
| 18-May-2018 | UAE; 18BR003845; SP; Brazil | **Species:** Canine<br>**Breed:** German Shepherd Dog<br>**Sex:** F<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other | 16-May-2018 | 18-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: as reported by the retail outlet via distributor, an unidentified, 45 days old, 6.5 kilogram, canine, female, intact, German Shepherd, received for the first time, a dose of FRONTLINE SPRAY (FL) (lot and exp date unknown, topically, with an unknown site of application ), applied by the owner |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Unknown<br>**Age:** 45.00 Day(s)<br>**Weight:** 6.5 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | on 16 May 2018, for tick treatment. The owner called the retail outlet and complained about the lack of efficacy, because her pet continued with ticks. According to the owner, she used FL in a tick that was in the environment and the thick remained alive. It is unknown if the environment has been treated, however, there are still ticks in the environment. There is also another dog in the same household but is unknown if FL was used in this animal. There is no further information available. |
| 17-May-2018 | UAE; 18BR003849; SP; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 11.00 Year(s)<br>**Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 06-Apr-2018 | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Belinha, 11 years old, 9 kilogram, canine, female, Mixed Breed, received 1 pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 4 Apr 2018. According to the owner 2 days after FL application (6 Apr 2018), she noticed fleas in her pet. The dog only stays inside the house and does not have contact with dogs from outside the household. The environment has been treated with an unidentified insecticide product. There are another 2 dogs in the same household with similar problem (see cases 18BR003815 and 18BR003850). It is unknown if FL was applied in the past. No further information is available. |
| 17-May-2018 | UAE; 18BR003850; SP; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 06-Apr-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Lilica, 7 years old, 10 kilogram, canine, female, Mixed Breed, received 1 pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 4 Apr 2018. According to the owner 2 days after FL application (6 Apr 2018), she noticed fleas in her pet. The dog only stays inside the house and does not have contact with dogs from outside the household. The environment has been treated with an unidentified insecticide product. There are another 2 dogs in the same household with similar problem (see cases 18BR003815 and 18BR003849). It is unknown if FL was applied in the past. No further information is available. |
| 21-May-2018 | UAE; 18BR003863; RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-May-2018* | 04-May-2018* | 3 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Frajola, a male mixed breed cat of 4 years old and 3 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON CAT (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on date not specified (1 May 2018 - chosen at random), for flea treatment. The pet was in good health prior to FL and has no history of adverse reactions. Three days after product application, the pet presented with application site hair loss and application site burn. No vet care was provided. This is the extent of the information available. UPDATE 29 MAY 2018 - Frajola was taken to the vet clinic on 22 May 2018 and showed improvement, but he is still presenting with hair loss at the application site. It is unknown if the cat remains under treatment or not. Revolution was usually applied to him with no issues. No further information is available. |
| 21-May-2018 | UAE; 18BR003866; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products | 21-Jan-2017* | 05-Feb-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Princesa, 4 years old, 3 kilogram, canine, female, Yorkshire, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the DVM, 4 months ago (21 Jan 2018 – estimated date) and 15 days after (5 Feb 2018 – estimated date). According to the owner, he continued to see fleas in his pet. There is also another dog in the same household who had a suspected lack of efficacy with FL |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | (see case 18BR003867). The environment has been treated with BUTOX®. The owner also used NEXGARD in both animal recently and complained (see cases 18BR003864 and 18BR003865). The environment has been treated with BUTOX®. No further information is available. UPDATE 23 MAY 2018 – According to the owner, he always used FRONTLINE to treat his animals (21 Jan 2017 – date chosen at random). No further information is available. |
| 21-May-2018 | UAE; 18BR003867; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 21-Jan-2017* | 05-Feb-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Julie, 3 years old, 4 kilogram, canine, female, Yorkshire, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the DVM 4 months ago (21 Jan 2018 – estimated date) and 15 days after (5 Feb 2018 – estimated date). According to the owner, he continued to see fleas in his pet. There is also another dog in the same household who had a suspected lack of efficacy with FL (see case 18BR003866). The environment has been treated with BUTOX®. The owner also used NEXGARD in both animal recently and complained (see cases 18BR003864 and 18BR003865). The environment has been treated with BUTOX®. No further information is available. UPDATE 23 MAY 2018 – According to the owner, he always used FRONTLINE to treat his animals (21 Jan 2017 – date chosen at random). No further information is available. |
| 21-May-2018 | UAE; 18BR003874; SP; Brazil | **Species:** Canine<br>**Breed:** Poodle (Toy)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 13 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 10-May-2018 | 11-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via social media, her dog was treated with FRONTLINE but continued to have fleas. UPDATE 22 MAY 2018 – Floquinho, a 4-year-old, 13 kg, male, crossbred Poodle x Cocker Spaniel, was treated with one vial of FRONTLINE SPOT-ON DOGS M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, for the first time, 12 days ago (10 May 2018), for flea treatment. Lack of efficacy suspected because the dog is still infested by fleas. Flea infestation prior to FL, environment treated with Butox, daily outdoor access, flea allergy dermatitis. There is no further information expected. |
| 21-May-2018 | UAE; 18BR003878; -; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 2.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 15-Apr-2018* | 21-May-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Eva, 2 years old, 2.8 kilogram, canine, female, Yorkshire, received for the second time a dose of FRONTLINE SPRAY (FL) (lot 001/17 exp date DEC 2018, topically, in the whole body), applied by the owner, on an unspecified date (15 May 2018 – date chosen at random), for flea treatment. The owner complained about the lack of efficacy because according to him, the fleas remains alive after application. According to the owner, he already has used FRONTLINE SPRAY (15 Apr 2018 – date chosen at random) and FRONTLINE in pipettes. It is unknown if he had any issues with the pipette. The first time the owner applied FL, he used in the neck, ears and tails, the second time was in the whole body. The environment has been treated with BUTOX® and TRIATOX®. There is also another dog in the same household with similar problem ( see case 18BR003879). No further information is available. |
| 21-May-2018 | UAE; 18BR003879; -; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** M<br>**Sex qualifier:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products | 15-Apr-2018* | 21-May-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Hercules, 3 years old, 4.5 kilogram, canine, male, Yorkshire, received for the second time a dose of FRONTLINE SPRAY (FL) (lot 001/17 exp date DEC 2018, topically, in the whole body), applied by the owner, on an unspecified date (15 May 2018 – date chosen at random), for flea treatment. The owner complained |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Age:** 3.00 Year(s)<br>**Weight:** 4.5 kg | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | about the lack of efficacy because according to him, the fleas remains alive after application. According to the owner, he already has used FRONTLINE SPRAY (15 Apr 2018 – date chosen at random) and FRONTLINE in pipettes. It is unknown if he had any issues with the pipette. The first time the owner applied FL, he used in the neck, ears and tails, the second time was in the whole body. The environment has been treated with BUTOX® and TRIATOX®. There is also another dog in the same household with similar problem ( see case 18BR003878). No further information is available. |
| 22-May-2018 | UAE; 18BR003886; PR; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 13.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 23-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Panda, a 13-year-old, 4 kg, female mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (005/17, Jun 2018), topic, base of skull and btw the shoulder blades, by the reporter, one month ago (22 Apr 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 15 days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the cat in the past. There is another cat in the same household that was treated with other company's product. No further information is available. |
| 21-May-2018 | UAE; 18BR003888; SP; Brazil | **Species:** Canine<br>**Breed:** Rottweiler<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 45 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 21-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Betoven, 3 years old, 45 kilogram, canine, male, Rottweiler, received 1 pipette of FRONTLINE PLUS DOG XL (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner 10 days ago (11 May 2018 – estimated date) for tick treatment. The owner complained about the lack of efficacy because she continues to see ticks in her animal. The environment has been treated with BUTOX®. There is also another dog in the same household with a similar problem who received NEXGARD (see case 18BR003889). It is unknown if the animal already received FL in the past. No further information is available. UPDATE 25 MAY 2018 - According to the owner, Betoven still has live ticks. No further information is available. |
| 22-May-2018 | UAE; 18BR003891; SP; Brazil | **Species:** Canine<br>**Breed:** Boxer<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 27 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 20-May-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female Boxer of 5 years old and 27 kg, was treated with FRONTLINE SPRAY (FL) (014/15, unknown exp date, topical, tail and btw the shoulder blades - incorrect application), applied by the reporter on 20 May 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites. The environment has been treated with deltamethrin. FL has been applied every week since date not specified (1 Jan 2017 - chosen at random). There is another dog in this household with the same issue (see case 18BR003892). No further information is expected. |
| 22-May-2018 | UAE; 18BR003892; SP; Brazil | **Species:** Canine<br>**Breed:** Pinscher (Miniature)<br>**Sex:** F | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products** | 01-Jan-2017* | 20-May-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Kiara, a female Pinscher of 8 years old and 6 kg, was treated with FRONTLINE SPRAY (FL) (014/15, unknown exp date, topical, tail and btw the shoulder blades - incorrect application), applied by the |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)
* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 6 kg | | | | **used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | reporter on 20 May 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites. The environment has been treated with deltamethrin. FL has been applied every week since date not specified (1 Jan 2017 - chosen at random). There is another dog in this household with the same issue (see case 18BR003891). No further information is expected. |
| 22-May-2018 | UAE; 18BR003898; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-May-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Fila, a 2-year-old, 5 kg, female, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (009/16, exp unknown), topic, whole body, by the reporter, on 17 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas . Flea infestation prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the cat in the past. 3 other cats of the same household that are also on FL were reported on 18BR003899, 18BR003900 and 18BR003901. No further information is available. |
| 22-May-2018 | UAE; 18BR003899; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-May-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Caan, a 2-year-old, 6 kg, male, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (009/16, exp unknown), topic, whole body, by the reporter, on 17 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas . Flea infestation prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the cat in the past. 3 other cats of the same household that are also on FL were reported on 18BR003898, 18BR003900 and 18BR003901. No further information is available. |
| 22-May-2018 | UAE; 18BR003900; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-May-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Goram, a 2-year-old, 6 kg, male, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (009/16, exp unknown), topic, whole body, by the reporter, on 17 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the cat in the past. 3 other cats of the same household that are also on FL were reported on 18BR003898, 18BR003899 and 18BR003901. No further information is available. |
| 22-May-2018 | UAE; 18BR003901; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-May-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dilan, a 2-year-old, 6 kg, male, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (009/16, exp unknown), topic, whole body, by the reporter, on 17 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas . Flea infestation prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the cat in the past. 3 other cats of the same household that are also on FL were reported on 18BR003898, 18BR003899 and 18BR003900. No further information is available. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 22-May-2018 | UAE; 18BR003902; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 22-Apr-2018 | 22-May-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Shacha, a female Shih Tzu of 6 years old and 5 kg, was treated, for the second time, with one vial of FRONTLINE SPOT-ON DOG S (FL) (004/17 and unknown exp date, topical, unknown location), applied by the reporter on 17 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has been treated with deltamethrin. FL was applied for the first time 30 days ago (22 Apr 2018). The dog has outdoor access. There is another dog in this household with the same issue (see case 18BR003903). No further information is expected. |
| 22-May-2018 | UAE; 18BR003903; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 22-May-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sushi, a male Shih Tzu of 10 years old and 7 kg, was treated with one vial of FRONTLINE SPOT-ON DOG S (FL) (004/17 and unknown exp date, topical, location unknown), applied by the reporter, 30 days ago (22 Apr 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has been treated with deltamethrin. The dog has outdoor access. It is unknown if FRONTLINE was applied to the dog in the past. There is another dog in this household with the same issue (see case 18BR003902). No further information is expected. |
| 22-May-2018 | UAE; 18BR003904; PE; Brazil | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 15-Mar-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, one female cat of unknown signalment was treated with FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Mar 2018 - chosen at random), for flea treatment. Lack of efficacy is suspected because the pet had fleas. Because of that, FRONTLINE PLUS CATS was applied and the pet is currently free of fleas. This is the extent of the information available. |
| 22-May-2018 | UAE; 18BR003905; PR; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Month(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 15-May-2018 | 22-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Katie, 6 months old, 9 kilogram, canine, female, Mixed Breed, received for the first time, a dose of FRONTLINE SPRAY (FL) (lot 001/17 exp date unknown, topically, in the whole body ), applied by the owner, on 15 May 2018 and yesterday (21 May 2018), for flea treatment. The owner complained about the lack of efficacy because she continues to see fleas in her animal,. According to the owner, animal already had fleas 30 days prior to treatment. The environment has been treated but the owner does not know the product´s name. The owner already used FRONTLINE PLUS in the past with no issues. There is also a cat in the same household with similar problem (see case 18BR003906). No further information is available. |
| 22-May-2018 | UAE; 18BR003906; PR; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products | 15-May-2018 | 22-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Liza, 1 year old, 2 kilogram, feline, female, Mixed Breed, received for the first time, a dose of FRONTLINE SPRAY (FL) (lot 001/17 exp date unknown, topically, in the whole body ), applied by the owner, on 15 May 2018 and yesterday (21 May 2018), for flea treatment. The owner complained about the lack of efficacy because she |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 2 kg | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | continues to see fleas in her animal. According to the owner, animal already had fleas 30 days prior to treatment. The environment has been treated but the owner does not know the product´s name. The owner already used FRONTLINE PLUS in the past with no issues. There is also a dog in the same household with similar problem (see case 18BR003905). No further information is available. |
| 20-May-2018 | UAE; 18BR003910; RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.50 Year(s)<br>**Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 20-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, more than one cat of unknown signalment were treated with FRONTLINE SPRAY (FL) (lot and exp unknown), by the reporter, on date not specified, for flea treatment. Lack of efficacy suspected because the cats continued to have fleas. Another bottle of FL was applied to them one week later; however it also did not work. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2017 chosen at random). UPDATE 23 MAY 2018 - Julieta, a 2.5-year-old, 4.5 kg, female, mixed breeds cat, was treated with FL, topic, whole body, 4 months ago approximately (presumed 20 Jan 2018, and one week later - 27 Jan 2018). FRONTLINE was not applied again since then. Flea infestation prior to FL, environment treated with Triatox, outdoor access denied. The amount of fleas has decreased. 4 other cats of the same household that were also on FL were reported on 18BR003933, 18BR003934, 18BR003935 and 18BR003936. No further information is available. |
| 21-May-2018 | UAE; 18BR003911; PR; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 05-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment was treated with one vial of FRONTLINE PLUS DOGS (size, lot and exp unknown), by the reporter, on date not specified (1 May 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. This is the extent of the information available. UPDATE 25 MAY 2018 - Ronaldinho, a 7-year-old, 6 kg, male, Lhasa Apso, was treated with FRONTLINE PLUS DOG S (FL), topic, base of skull and btw the shoulder blades, by the reporter, 3 weeks ago (4 May 2018). Flea infestation one week prior to FL, environment treated (details unknown). It is unknown if FRONTLINE was applied to the dog in the past. There is no further information expected. |
| 21-May-2018 | UAE; 18BR003912; SP; Brazil | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 15-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one cat of unknown signalment was treated with one vial of FRONTLINE for cats (presentation, lot and exp unknown), 'according to the product instructions' (topic, between the shoulder blades), by the reporter, one week ago (14 May 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. This is the extent of the information available. |
| 23-May-2018 | UAE; 18BR003930; RJ; Brazil | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** M<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | N/A | 19-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, her pet was treated with FRONTLINE 10 days ago, but she discovered one tick on her pet at the day of the report. UPDATE 23 MAY 2018 - Davi, an 1.9-year-old, 2 kg, male, |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** 1.90 Year(s)<br>**Weight:** 2 kg | | | | 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | Chihuahua, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, for tick prevention. Lack of efficacy suspected because she discovered one tick on her dog 10 days post FL. Environment not treated. Since FL did not work, Simparic was given and Davi has no ticks anymore. No further information is available. |
| 20-May-2018 | UAE;<br>18BR003933;<br>RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Month(s)<br>**Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jul-2017* | 20-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Juju, a 12-month-old, 2.5 kg, female, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, whole body, by the reporter, 4 months ago approximately (presumed 20 Jan 2018). Lack of efficacy suspected because the cat continued to have fleas. Another bottle of FL was applied one week later (presumed 27 Jan 2018), however it also did not work. FRONTLINE was not applied again since then. Flea infestation prior to FL, environment treated with Triatox, outdoor access denied. The amount of fleas has decreased. FRONTLINE was applied in the past with no issues (date not specified – 1 Jul 2017 chosen at random for first dose). 4 other cats of the same household that were also on FL were reported on 18BR003910, 18BR003934, 18BR003935 and 18BR003936. No further information is available. |
| 20-May-2018 | UAE;<br>18BR003934;<br>RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Month(s)<br>**Weight:** 2.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Sep-2017* | 20-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pintinha, a 9-month-old, 2.6 kg, female, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, whole body, by the reporter, 4 months ago approximately (presumed 20 Jan 2018). Lack of efficacy suspected because the cat continued to have fleas. Another bottle of FL was applied one week later (presumed 27 Jan 2018), however it also did not work. FRONTLINE was not applied again since then. Flea infestation prior to FL, environment treated with Triatox, outdoor access denied. The amount of fleas has decreased. FRONTLINE was applied in the past with no issues (date not specified – 1 Sep 2017 chosen at random for first dose). 4 other cats of the same household that were also on FL were reported on 18BR003910, 18BR003933, 18BR003935 and 18BR003936. No further information is available. |
| 20-May-2018 | UAE;<br>18BR003935;<br>RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Month(s)<br>**Weight:** 2.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Sep-2017* | 20-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Olhinho, an 8-month-old, 2.6 kg, male, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, whole body, by the reporter, 4 months ago approximately (presumed 20 Jan 2018). Lack of efficacy suspected because the cat continued to have fleas. Another bottle of FL was applied one week later (presumed 27 Jan 2018), however it also did not work. FRONTLINE was not applied again since then. Flea infestation prior to FL, environment treated with Triatox, outdoor access denied. The amount of fleas has decreased. FRONTLINE was applied in the past with no issues (date not specified – 1 Sep 2017 chosen at random for first dose). 4 other cats of the same household that were also on FL were reported on 18BR003910, 18BR003933, 18BR003934 and 18BR003936. No further information is available. |
| 20-May-2018 | UAE; | **Species:** Feline | 1 | 1 | 0 | **Product used:** | 01-Jan-2017* | 20-Jan-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | 18BR003936; RJ; Brazil | **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.50 Year(s) **Weight:** 6 kg | | | | FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | Romeu, a 2.5-year-old, 6 kg, male, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, whole body, by the reporter, 4 months ago approximately (presumed 20 Jan 2018). Lack of efficacy suspected because the cat continued to have fleas. Another bottle of FL was applied one week later (presumed 27 Jan 2018), however it also did not work. FRONTLINE was not applied again since then. Flea infestation prior to FL, environment treated with Triatox, outdoor access denied. The amount of fleas has decreased. FRONTLINE was applied in the past with no issues (date not specified – 1 Jan 2017 chosen at random for first dose). 4 other cats of the same household that were also on FL were reported on 18BR003910, 18BR003933, 18BR003934 and 18BR003935. No further information is available. |
| 23-May-2018 | UAE; 18BR003939; SP; Brazil | **Species:** Canine **Breed:** Border Collie **Sex:** M **Sex qualifier:** Unknown **Age:** 4.50 Year(s) **Weight:** 24 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 19-May-2018 | 20-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Haton, a male Border Collie of 4.5 years old and 24 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date are unknown, topical, location unknown), applied by the reporter on 19 May 2018, for flea/tick control. One day later, the pet started scratching himself and he has a lot of small lumps around his body. The owner administered an antihistamine and a corticoid, but the symptoms are still ongoing. No further information is available. |
| 23-May-2018 | UAE; 18BR003943; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 23-May-2018 | 23-May-2018* | 0 Day(s) | D-C | Suspected Adverse Event: As reported by the attending veterinarian, Mitz, a male mixed breed cat of approximately 1 year old and unknown weight, was treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the pet owner 'today' (23 May 2018). Some minutes after product application, the pet presented hypersalivation, urticaria and erythema. The animal was treated with corticosteroid, atropine and fluid therapy. The pet remains under vet supervision. A similar case was reported on 18BR003944. No further information is available. |
| 23-May-2018 | UAE; 18BR003944; RS; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 23-May-2018 | 02-Jan-2018 | N/A | D-D | Suspected Adverse Event: As reported by the attending veterinarian, an unknown number of cats were treated with FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown), applied by an unknown person on date not specified (1 Jan 2018 – chosen at random). On unknown date (2 Jan 2018 – chosen at random), the cats had an reaction (details were not provided). A similar case was reported on 18BR003943. No further information is available. |
| 21-May-2018 | UAE; 18BR003946; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other | N/A | 05-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the owner: 25 (Vinte Cinco), age unknown, adopted 8 months ago, 3 kilogram, canine, male, Mixed Breed, received, a dose of FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by an unknown person, approximately 15 days ago (9 May 2018 – |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 3 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | estimated date), in a campaign held at a veterinary clinic for an unknown reason. According to the owner the animal presented hypersalivation and tongue exposition after FL application, drink water and recovered. The adverse event last for 2 hours. There are another 2 dogs of the owner who presented a similar reaction (see cases 18BR003947 and 18BR003948) and 2 other dogs also presented alopecia (see cases 18BR003949 and 18BR003950). The owner also complained about the lack of efficacy but do not specify which or how many animals had it (see case 18BR003951). According to the owner the product was in 500 mL bottles. The owner has 9 dogs in total and all of them received FL. No further information is available. UPDATE 24 MAY 2018 – The owner sent the contact from the clinic and the DVM where the application campaign was held. No further information is available. UPDATE 25 MAY 2018 - FRONTLINE SPRAY (FL) (010/16, exp unknown) was applied topic, between the shoulder blades, by DVM, on 5 May 2018. The veterinarian was contacted and she reported that 25 was high infested by ticks, in poor health condition and presenting with ocular discharge prior to FL. SLOE case reported on 18BR004009. There is no further information expected. |
| 21-May-2018 | UAE; 18BR003947; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 05-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the owner: Huguinho, 1 year old, 3 kilograms, canine, male, Shih Tzu, received, a dose of FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by an unknown person, approximately 15 days ago (9 May 2018 – estimated date), in a campaign held at a veterinary clinic for an unknown reason. According to the owner the animal presented hypersalivation and tongue exposition after FL application, drunk water and recovered. The adverse event last for 2 hours. There are another 2 dogs of the owner who presented a similar reaction (see cases 18BR003946 and 18BR003948) and 2 other dogs also presented alopecia (see cases 18BR003949 and 18BR003950). The owner also complained about the lack of efficacy but do not specify which or how many animals had it (see case 18BR003951). According to the owner the product was in 500 mL bottles.The owner has 9 dogs in total and all of them received FL. No further information is available. UPDATE 24 MAY 2018 – The owner sent the contact from the clinic and the DVM where the application campaign was held. No further information is available. UPDATE 25 MAY 2018 - FRONTLINE SPRAY (FL) (010/16, exp unknown) was applied topic, between the shoulder blades, by DVM, on 5 May 2018. The veterinarian was contacted and she reported that Huguinho was high infested by ticks, in poor health condition and presenting with ocular discharge prior to FL. SLOE case reported on 18BR004010. There is no further information expected. |
| 21-May-2018 | UAE; 18BR003948; SP; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No | N/A | 05-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the owner: Mel, 6 year old, 6 kilograms, canine, female, Lhasa Apso, received, a dose of FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by an unknown person, approximately 15 days ago (9 May 2018 – estimated date), in a campaign held at a veterinary clinic for an unknown reason. According to the owner the animal presented hypersalivation and tongue exposition after FL application, drunk water and recovered. The adverse event last for 2 hours. There are another 2 dogs of the owner who presented a similar reaction (see cases 18BR003946 and 18BR003947) and 2 other dogs also presented alopecia (see cases 18BR003949 and 18BR003950). The owner also complained about the lack of |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | (Treatment / vaccination program not respected) | | | | | efficacy but do not specify which or how many animals had it (see case 18BR003951). According to the owner the product was in 500 mL bottles.The owner has 9 dogs in total and all of them received FL. No further information is available. UPDATE 24 MAY 2018 – The owner sent the contact from the clinic and the DVM where the application campaign was held. No further information is available. UPDATE 25 MAY 2018 - FRONTLINE SPRAY (FL) (010/16, exp unknown) was applied topic, between the shoulder blades, by DVM, on 5 May 2018. The veterinarian was contacted and she reported that Mel was high infested by ticks, in poor health condition and presenting with ocular discharge prior to FL. SLOE case reported on 18BR004011. There is no further information expected. |
| 21-May-2018 | UAE; 18BR003949; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Lactating **Age:** 30.00 Month(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 10-May-2018* | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the owner: Neguinha, 30 months old, 8 kilograms, canine, female, Shih Tzu, lactating, received, a dose of FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by an unknown person, approximately 15 days ago (9 May 2018 – estimated date), in a campaign held at a veterinary clinic for an unknown reason. According to the owner, the animal presented alopecia on the application site 1 day after FL (10 May 2018 – estimated date). According to the owner, the animal was taken to 2 DVM who said that FL had caused the hair loss. The owner will take the animal to a third veterinarian. There is another dogs of the owner who presented a similar reaction (see case 18BR003950) and 3 other dogs also presented other adverse events (see cases 18BR003946 to 18BR003948). The owner also complained about the lack of efficacy but do not specify which or how many animals had it (see case 18BR003951). According to the owner the product was in 500 mL bottles. The owner has 9 dogs in total and all of them received FL. No further information is available. UPDATE 25 MAY 2018 – The owner took Neguinha to the DVM who administered corticoid to decrease the reddening skin. According to the DVM, it was not the first case from dogs that receive products application in campaigns and presented adverse events as she heard from a colleague (event or product not specified). No further information is available. UPDATE 25 MAY 2018 - FRONTLINE SPRAY (FL) (010/16, exp unknown) was applied topic, between the shoulder blades, by DVM, on 5 May 2018. The veterinarian was contacted and she reported that Neguinha was high infested by ticks, in poor health condition and presenting with ocular discharge prior to FL, but no hair loss noticed at the application site (prior to FL). SLOE case reported on 18BR004012. There is no further information expected. |
| 21-May-2018 | UAE; 18BR003950; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 3.50 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / | N/A | 06-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the owner: Malan, 42 months old, 7 kilograms, canine, male, Shih Tzu, lactating, received, a dose of FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by an unknown person, approximately 15 days ago (9 May 2018 – estimated date), in a campaign held at a veterinary clinic for an unknown reason. According to the owner, the animal presented alopecia on the application site 1 day after FL (10 May 2018 – estimated date).According to the owner, the animal was taken to 2 DVMs who said that FL had caused the hair loss. The owner will take the animal to a third veterinarian. There is another dogs of the owner who presented a similar reaction (see case 18BR003949) and 3 other dogs also presented other adverse events (see cases |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | vaccination program not respected) | | | | | 18BR003946 to 18BR003948). The owner also complained about the lack of efficacy but do not specify which or how many animals had it (see case 18BR003951). According to the owner the product was in 500 mL bottles. The owner has 9 dogs in total and all of them received FL. Malan already received FRONTLINE in pipettes in the past. No further information is available. UPDATE 24 MAY 2018 – The owner sent the contact from the clinic and the DVM where the application campaign was held. No further information is available. UPDATE 25 MAY 2018 – Malan is a 3.5 year-old, male, Shih Tzu. FRONTLINE SPRAY (FL) (010/16, exp unknown) was applied topic, between the shoulder blades, by DVM, on 5 May 2018. The veterinarian was contacted and she reported that Malan was high infested by ticks, in poor health condition and presenting with ocular discharge prior to FL, but no hair loss noticed at the application site (prior to FL). SLOE case reported on 18BR004013. There is no further information expected. |
| 21-May-2018 | UAE; 18BR003951; SP; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 4 | 4 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 06-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: 9 dogs received a dose of FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by an unknown person, approximately 15 days ago (9 May 2018 – estimated date), in a campaign held at a veterinary clinic for an unknown reason. The owner complained about the lack of efficacy, because an unknown number of these dogs are with ticks. The owner does not specify which or how many animals have ticks. The owner also report cases of adverse events regarding those animals (see cases 18BR003946 to 18BR003950). No further information is available. UPDATE 24 MAY 2018 – The owner sent the contact from the clinic and the DVM where the application campaign was held. No further information is available. UPDATE 25 MAY 2018 - FRONTLINE SPRAY (FL) (010/16, exp unknown) was applied to 4 dogs of unknown signalment, topic, between the shoulder blades, by DVM, on 5 May 2018, for tick treatment. The dogs were in poor health condition prior and high infested by ticks prior to FL. Lack of efficacy suspected because they continued to have ticks . Other details were not provided. 5 other dogs that are also on FL were reported on 18BR004009, 18BR004010, 18BR004011, 18BR004012 and 18BR004013. There is no further information expected. |
| 24-May-2018 | UAE; 18BR003953; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 3.5 kg | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 24-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Ana Clara, a female mixed breed cat of 8 months old and 3.5 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 22 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. A similar case was reported on 18BR003954. There is a dog in this household that was treated with FRONTLINE and it has no issue. No further information is expected. |
| 24-May-2018 | UAE; 18BR003954; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON | N/A | 24-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Maria Graça, a female mixed breed cat of 4 years old and 4 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 22 May 2018, for flea treatment. Lack of efficacy |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 4 kg | | | | **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. A similar case was reported on 18BR003953. There is a dog in this household that was treated with FRONTLINE and it has no issue. No further information is expected. |
| 22-May-2018 | UAE; 18BR003955; SC; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 13 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 25-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, 3 dogs were treated with FRONTLINE, however she believes that FRONTLINE was not working because they continued to have fleas. UPDATE 24 MAY 2018 – Boby, a 6-year-old, 13 kg, male, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 24 Apr 2018, for flea treatment. Lack of efficacy suspected because the amount of fleas decreased, however the dog is still infested. Flea infestation prior to FL, environment not treated. FRONTLINE was usually applied every 3 months since date not specified (1 Jan 2017 chosen at random). 2 other dogs reported on 18BR003956 and 18BR003957. No further information is available. |
| 22-May-2018 | UAE; 18BR003956; SC; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 12 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 25-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, 3 dogs were treated with FRONTLINE, however she believes that FRONTLINE was not working because they continued to have fleas. UPDATE 24 MAY 2018 – Jhoy, a 3-year-old, 12 kg, male, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 24 Apr 2018, for flea treatment. Lack of efficacy suspected because the amount of fleas decreased, however the dog is still infested. Flea infestation prior to FL, environment not treated. FRONTLINE was usually applied every 3 months since date not specified (1 Jan 2017 chosen at random). 2 other dogs reported on 18BR003955 and 18BR003957. No further information is available. |
| 22-May-2018 | UAE; 18BR003957; SC; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Month(s) **Weight:** 9.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jul-2017* | 25-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, 3 dogs were treated with FRONTLINE, however she believes that FRONTLINE was not working because they continued to have fleas. UPDATE 24 MAY 2018 – Piquininho, a 12-month-old, 9.5 kg, male, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 24 Apr 2018, for flea treatment. Lack of efficacy suspected because the amount of fleas decreased, however the dog is still infested. Flea infestation prior to FL, environment not treated. FRONTLINE was usually applied every 3 months since date not specified (1 Jul 2017 chosen at random). 2 other dogs reported on 18BR003955 and 18BR003956. No further information is available. |
| 24-May-2018 | UAE; 18BR003958; SP; Brazil | **Species:** Feline **Breed:** Siamese **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous | 24-Mar-2018* | 25-Apr-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dunga, a male Siamese of 3 years old and 5 kg, was treated with FRONTLINE SPRAY (FL) (013/16, Nov 2018, topical, parts of the body - incorrect application), applied by the reporter on 20 May 2018 (estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL has been applied every week since 2 months ago (24 Mar 2018 - estimated date). Similar |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | cases reported on 18BR003959 and 18BR003960. There are two dogs in this household that were not treated and they have no issue. No further information is expected. |
| 24-May-2018 | UAE; 18BR003959; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 24-Mar-2018* | 25-Mar-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mika, a female mixed breed cat of 5 years old and 6 kg, was treated with FRONTLINE SPRAY (FL) (013/16, Nov 2018, topical, parts of the body - incorrect application), applied by the reporter on 20 May 2018 (estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL has been applied every week since 2 months ago (24 Mar 2018 - estimated date). Similar cases reported on 18BR003958 and 18BR003960. There are two dogs in this household that were not treated and they have no issue. No further information is expected. |
| 24-May-2018 | UAE; 18BR003960; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 24-Mar-2018* | 25-Mar-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Cicinha, a female mixed breed cat of 1 year old and 4 kg, was treated with FRONTLINE SPRAY (FL) (013/16, Nov 2018, topical, parts of the body - incorrect application), applied by the reporter on 20 May 2018 (estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL has been applied every week since 2 months ago (24 Mar 2018 - estimated date). Similar cases reported on 18BR003958 and 18BR003959. There are two dogs in this household that were not treated and they have no issue. No further information is expected. |
| 24-May-2018 | UAE; 18BR003966; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 17-May-2017* | 24-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Nana, 2 years old, 15 kilogram, canine, unknown sex, Mixed Breed, split a pipette with a syringe and applied around 0.68 mL of FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 17 May 2018, for flea treatment. The owner complained about the lack of efficacy, because she continues to see fleas in her animal. According to the owner, animal already had fleas 4 days prior to treatment. There are another 3 animals in the same household with a similar condition (see cases 18BR003967 to 18BR003969). The environment has not been treated. The owner already used FL in the past for flea and tick treatment with no issues (17 May 2017 – date chosen at random). No further information is available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 24-May-2018 | UAE; 18BR003967; SP; Brazil | **Species:** Canine **Breed:** Basset Hound **Sex:** M **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 17-May-2017* | 24-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Fred, 11 years old, 4 kilogram, canine, male, Basset Hound, split a pipette with a syringe and applied around 0.68 mL of FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 17 May 2018, for flea treatment. The owner complained about the lack of efficacy, because she continues to see fleas in her animal. According to the owner, animal already had fleas 4 days prior to treatment. There are another 3 animals in the same household with a similar condition (see cases 18BR003966, 18BR003968 and 18BR003969). The environment has not been treated. The owner already used FL in the past for flea and tick treatment with no issues (17 May 2017 – date chosen at random). No further information is available. |
| 24-May-2018 | UAE; 18BR003968; SP; Brazil | **Species:** Canine **Breed:** Basset Hound **Sex:** M **Sex qualifier:** Unknown **Age:** 126.00 Month(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 17-May-2017* | 24-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Floque, 126 months old, 7 kilogram, canine, male, Basset Hound, split a pipette with a syringe and applied around 0.68 mL of FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 17 May 2018, for flea treatment. The owner complained about the lack of efficacy, because she continues to see fleas in her animal. According to the owner, animal already had fleas 4 days prior to treatment. There are another 3 animals in the same household with a similar condition (see cases 18BR003966, 18BR003967 and 18BR003969). The environment has not been treated. The owner already used FL in the past for flea and tick treatment with no issues (17 May 2017 – date chosen at random). No further information is available. |
| 24-May-2018 | UAE; 18BR003969; SP; Brazil | **Species:** Canine **Breed:** Doberman **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 58 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 17-May-2017* | 24-May-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner: Maya, 4 years old, 58 kilogram, canine, female, Doberman, received a pipette of FRONTLINE PLUS DOG XL (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 17 May 2018, for flea treatment. The owner complained about the lack of efficacy, because she continues to see fleas in her animal. According to the owner, animal already had fleas 4 days prior to treatment. There are another 3 animals in the same household with a similar condition (see cases 18BR003966 to 18BR003968). The environment has not been treated. The owner already used FL in the past for flea and tick treatment with no issues (17 May 2017 – date chosen at random). No further information is available. |
| 24-May-2018 | UAE; 18BR003973; -; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 3.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products | N/A | 24-May-2018* | 23 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female Yorkshire of 3.2 kg (other signalment is unknown) was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot, exp date, route and location are unknown), applied by the reporter on 1 May 2017 (estimated date), for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites. This is the extent of the information available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **Route:** unknown **Was the product used ok?:** Unknown to Company | | | | | |
| 22-May-2018 | UAE; 18BR003975; MG; Brazil | **Species:** Canine **Breed:** Rottweiler **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 22-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a female Rottweiler of unknown signalment was treated with FRONTLINE PLUS (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 12 May 2018, for tick treatment. Lack of efficacy is suspected because the pet is infested by ticks. This is the extent of the information available. |
| 23-May-2018 | UAE; 18BR003976; SP; Brazil | **Species:** Canine **Breed:** Dalmatian **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 29 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 10-May-2018* | 11 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Zara, a female Dalmatian of 6 years old and 29 kg, was treated with one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 29 Apr 2018, for flea/tick control. Lack of efficacy is suspected because fleas were found on the pet. The environment has not been treated and FL was applied a long time ago (first application was not provided - 1 Jan 2017 chosen at random). There is another dog with similar problem (see case 18BR003977). No further information is expected. |
| 23-May-2018 | UAE; 18BR003977; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 05-May-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female small crossbred dog of 10 years old and 10 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 29 Apr 2018, for flea/tick control. Lack of efficacy is suspected because the pet has ectoparasites. The environment has not been treated and FL was applied 3 months ago (first application was not provided - 1 Jan 2017 chosen at random). The pet was in good health prior to FL and has no history of adverse reactions. Ten days after product application, Mel presented apathy, decreased appetite and panting. On 12 May 2018, Mel was taken to the vet and a CBC test showed leucopenia, eosinophilia and monocytosis. Tick-borne disease was diganosed by the vet. The pet is being treated with doxycycline, prednisolone and Leucogen®. There is another dog with similar problem (see case 18BR003976). No further information is expected. |
| 25-May-2018 | UAE; 18BR003984; SC; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products | 01-Jan-2017* | 25-May-2018* | 26 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Luck, a male Shih Tzu of 2 years old and 4.5 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 29 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. No further information is expected. UPDATE 29 MAY 2018 - Luck is |

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| | | | | | | **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | still infested by fleas and scratching. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first application on date not specified - 1 Jan 2017 chosen at random). This time, the owner mentioned environmental treatment (details unknown). There is no further information expected. |
| 25-May-2018 | UAE; 18BR003985; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 3.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 25-May-2018 | 0 Day(s) | D-C | Suspected Adverse Event: As reported by the veterinarian, Cherry, a 7-year-old, 3.1 kg, female, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, whole body, by the pet owner, today (25 May 2018) morning. The cat licked her paw and she immediately started experiencing convulsion. Cherry was taken to the vet clinic and remains under treatment with Diazepam. The cat is also presenting with hematuria, and the convulsion is still ongoing even with treatment. Other details were not provided. No further information is available. |
| 24-May-2018 | UAE; 18BR003992; SC; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Month(s) **Weight:** 3 kg | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female dog of 11 months old and unknown weight received FRONTLINE PLUS (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 May 2018 - chosen at random). The owner believes that FL is not working (details were not provided. No further information is available. UPDATE 25 MAY 2018 – The owner informed that she has 3 dogs and was used to apply FL in 2 of them. During the month of April (15 Apr 2018 – estimated date) she applied in all 3 dogs, but the young one, remained with fleas. Bebezinha, 11 months old, 3 kilogram, canine, female, mixed breed, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topically, between the shoulder blades ), for flea treatment. The environment has been treated but the owner did not inform the product´s name. On January the owner applied FL in only 1 of her dogs (patient not specified) and had no issues. It is unknown if the animal already received FL in the past . No further information is available. |
| 25-May-2018 | UAE; 18BR003998; SP; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 18.00 Year(s) **Weight:** 30 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 01-Apr-2018* | 25-May-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Rabija, a female large crossbred dog of 18 years old and 30 kg, was treated, for the second time, with FRONTLINE (unsubstantiated) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 10 May 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with deltamethrin. FL was applied for the first time on date not specified (1 Apr 2018 - chosen at random). The pet has no outdoor access. No further information is expected. |
| 25-May-2018 | UAE; 18BR003999; -; Brazil | **Species:** Canine **Breed:** Australian Cattle Dog **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other | 15-May-2016* | 25-May-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one unidentified dog, 25 kilogram, received FRONTLINE (unsubstantiated) (lot, exp date, topically, between the shoulder blades), applied by the reporter on date not specified (15 May 2018 - chosen at random) for flea treatment. The owner complained about the lack of efficacy because according to her, the product did not work. According to the owner, FL was applied |

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| | | **Weight:** 25.000 - 30 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | following the instructions in label. The environmental conditions are unknown. There is another dog in the same household with similar problem (see case 18BR004000). It is unknown if the animal already received FL in the past. No further information is available. UPDATE 29 MAY 2018 – Taura, 3 years old, 25 to 30 kilogram, canine, female, Australian Cattle Dog, received 1 pipette of FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topically, between the shoulder blades). The owner said that she uses FL frequently every 3 months (first time,15 May 2016 – date chosen at random). The owner rarely walks with the animal on the street. The house has a place with grass and the gate has 'openings' allowing the contact with another dogs on the street. The owner also complained about a previous application (15 Feb 2018 – date chosen at random), because her animals were scratching. The owner is not sure if FL was correctly applied previously. No information regarding environmental treatment was provided. No further information is available. |
| 25-May-2018 | UAE; 18BR004000; RS; Brazil | **Species:** Canine<br>**Breed:** Australian Cattle Dog<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 30 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 15-May-2016* | 28-May-2018* | 13 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one unidentified dog, around 30 kilogram, received FRONTLINE (unsubstantiated) (lot, exp date, topically, between the shoulder blades), applied by the reporter on date not specified (15 May 2018 - chosen at random) for flea treatment. The owner complained about the lack of efficacy because according to her, the product did not work. According to the owner, FL was applied following the instructions in label. The environmental conditions are unknown. There is another dog in the same household with similar problem (see case 18BR003999). It is unknown if the animal already received FL in the past. No further information is available. UPDATE 29 MAY 2018 – Lucky, 5 years old, canine, male, Australian Cattle Dog, received 1 pipette of FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topically, between the shoulder blades). The owner said that she uses FL frequently every 3 months (first time,15 May 2016 – date chosen at random). The owner rarely walks with the animal on the street. The house has a place with grass and the gate has 'openings' allowing the contact with another dogs on the street. The owner also complained about a previous application (15 Feb 2018 – date chosen at random), because her animals were scratching. The owner is not sure if FL was correctly applied previously. No information regarding environmental treatment was provided. No further information is available. |
| 28-May-2018 | UAE; 18BR004003; PR; Brazil | **Species:** Canine<br>**Breed:** Basset Hound<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 62.00 Day(s)<br>**Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 28-May-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Niepzsche, a male Basset x Pinscher of 62 days old and 2.5 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 24 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. No further information is expected. |
| 25-May-2018 | UAE; 18BR004009; SP; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg) | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products** | N/A | 06-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner and the veterinarian, 25, a 3 kg, male, crossbred dog (age unknown), was treated with FRONTLINE SPRAY (FL) (010/16, exp unknown), topic, between the shoulder blades, by DVM, on 5 May |

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| | | **Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 3 kg | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | 2018, for tick treatment. 25 was in poor health condition and high infested by ticks prior to FL. Lack of efficacy suspected because the dog continued to have ticks. Other details were not provided. Similar cases reported on 18BR003951, 18BR004010, 18BR00004011, 18BR004012 and 18BR004013. No further information is available. |
| 25-May-2018 | UAE; 18BR004010; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Month(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 06-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner and the veterinarian, Huguinho, a 12-month-old, 3 kg, male, Shih Tzu, was treated with FRONTLINE SPRAY (FL) (010/16, exp unknown), topic, between the shoulder blades, by DVM, on 5 May 2018, for tick treatment. Huguinho was in poor health condition and high infested by ticks prior to FL. Lack of efficacy suspected because the dog continued to have ticks. Other details were not provided. Similar cases reported on 18BR003951, 18BR004009, 18BR00004011, 18BR004012 and 18BR004013. No further information is available. |
| 25-May-2018 | UAE; 18BR004011; SP; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 06-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner and the veterinarian, Mel, a 6-year-old, 6 kg, female, Lhasa Apso, was treated with FRONTLINE SPRAY (FL) (010/16, exp unknown), topic, between the shoulder blades, by DVM, on 5 May 2018, for tick treatment. Mel was in poor health condition and high infested by ticks prior to FL. Lack of efficacy suspected because the dog continued to have ticks. Other details were not provided. Similar cases reported on 18BR003951, 18BR004009, 18BR00004010, 18BR004012 and 18BR004013. No further information is available. |
| 25-May-2018 | UAE; 18BR004012; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Lactating<br>**Age:** 2.50 Year(s)<br>**Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 06-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner and the veterinarian, Neguinha, a 2.5-year-old, 8 kg approximately, lactant female, Shih Tzu, was treated with FRONTLINE SPRAY (FL) (010/16, exp unknown), topic, between the shoulder blades, by DVM, on 5 May 2018, for tick treatment. Neguinha was in poor health condition and high infested by ticks prior to FL. Lack of efficacy suspected because the dog continued to have ticks . Other details were not provided. Similar cases reported on 18BR003951, 18BR004009, 18BR00004010, 18BR004011 and 18BR004013. No further information is available. |

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| 25-May-2018 | UAE; 18BR004013; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 3.50 Year(s) **Weight:** 7 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 06-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner and the veterinarian, Malan, a 3.5-year-old, 7 kg, male, Shih Tzu, was treated with FRONTLINE SPRAY (FL) (010/16, exp unknown), topic, between the shoulder blades, by DVM, on 5 May 2018, for tick treatment. Malan was in poor health condition and high infested by ticks prior to FL. Lack of efficacy suspected because the dog continued to have ticks. Other details were not provided. Similar cases reported on 18BR003951, 18BR004009, 18BR00004010, 18BR004011 and 18BR004012. No further information is available. |
| 28-May-2018 | UAE; 18BR004014; MG; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 18-May-2018 | 18-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Teco, a 10-year-old, 3 kg, male, Poodle Toy, was treated with FRONTLINE SPRAY (FL) (012/16, exp unknown), topic, whole body, by the reporter, 10 days ago (18 May 2018) and yesterday (27 May 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 1 week prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. 3 other pets of the same household that are also on FL were reported on 18BR004015, 18BR004016 and 18BR004017. No further information is available. |
| 28-May-2018 | UAE; 18BR004015; MG; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 800 gms | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 18-May-2018 | 18-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pituco, a 6-year-old, 800 G, male, Poodle Toy, was treated with FRONTLINE SPRAY (FL) (012/16, exp unknown), topic, whole body, by the reporter, 10 days ago (18 May 2018) and yesterday (27 May 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 1 week prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. 3 other pets of the same household that are also on FL were reported on 18BR004014, 18BR004016 and 18BR004017. No further information is available. |
| 28-May-2018 | UAE; 18BR004016; MG; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | 18-May-2018 | 18-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Jimy, a 4-year-old, 1 kg, male, Poodle Toy, was treated with FRONTLINE SPRAY (FL) (012/16, exp unknown), topic, whole body, by the reporter, 10 days ago (18 May 2018) and yesterday (27 May 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 1 week prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. 3 other pets of the same household that are also on FL were reported on 18BR004014, 18BR004015 and 18BR004017. No further |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** No (Treatment / vaccination program not respected) | | | | | information is available. |
| 28-May-2018 | UAE; 18BR004017; MG; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 18-May-2018 | 18-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Fofinha, a 7-year-old, 1.5 kg, female, Poodle Toy, was treated with FRONTLINE SPRAY (FL) (012/16, exp unknown), topic, whole body, by the reporter, 10 days ago (18 May 2018) and yesterday (27 May 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 1 week prior to FL, environment treated with Butox. It is unknown if FRONTLINE was applied to the dog in the past. 3 other pets of the same household that are also on FL were reported on 18BR004014, 18BR004015 and 18BR004016. No further information is available. |
| 28-May-2018 | UAE; 18BR004019; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 40.00 Day(s) **Weight:** 300 gms | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 20-May-2018 | 24-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Lion, a male mixed breed cat of 40 days old and 300 g, was treated with FRONTLINE SPRAY (FL) (017/16, Nov 2018, topical, btw the shoulder blades - incorrect application), applied by the reporter on 20 May 2018, 21 May 2018 and 22 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. There are 2 more animals in this household that were treated with another product against fleas and they have no issue. No further information is expected. |
| 28-May-2018 | UAE; 18BR004020; SP; Brazil | **Species:** Canine **Breed:** Shar Pei **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 20-May-2017* | 28-May-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mozar, 3 years old, 10 kilogram, canine, male, Shar Pei, received 1 vial of FRONTLINE PLUS DOG L (lot 015/17, exp date MAR 2019, topically, between the shoulder blades), applied by the reporter on 20 May 2018 for tick treatment. The owner complained about the lack of efficacy because she applies FL monthly and since the previous application on April (20 Apr 2018 – estimated date) she keeps seeing ticks in her animal. According to the owner, animal already had ticks 2 days prior to application (not specified if on April or May). The environment has been treated by a company with a proper product. There is also another dog in the same household with a similar problem (see case 18BR004021). No further information is available. |
| 28-May-2018 | UAE; 18BR004021; SP; Brazil | **Species:** Canine **Breed:** Canine (unknown) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 20-May-2017* | 28-May-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lili, 7 years old, 43 kilogram, canine, female, unknown breed, received 1 vial of FRONTLINE PLUS DOG XL (lot 016/17, exp |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 43 kg | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | date MAR 2019, topically, between the shoulder blades), applied by the reporter on 20 May 2018 for tick treatment. The owner complained about the lack of efficacy because she applies FL monthly and since the previous application in April (20 Apr 2018 – estimated date) she keeps seeing ticks in her animal. According to the owner, animal already had ticks 2 days prior to application (not specified if on April or May). The environment has been treated by a company with a proper product. There is also another dog in the same household with a similar problem (see case 18BR004020). No further information is available. |
| 29-May-2018 | UAE; 18BR004023; SC; Brazil | **Species:** Canine<br>**Breed:** Pointer (German Short-Haired)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 15.00 Year(s)<br>**Weight:** 32 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2016* | 29-May-2018* | 3 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Thor, a male German Shorthaired Pointer of 15 years old and 32 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS L (FL) (012/16 and unknown exp date, topical, btw the shoulder blades), applied by the reporter 3 weeks ago (8 May 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2016 chosen at random). There are two more dogs in this household with the same issue (see cases 18BR004024 and 18BR004025). No further information is expected. |
| 29-May-2018 | UAE; 18BR004024; SC; Brazil | **Species:** Canine<br>**Breed:** Rottweiler<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 38 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jul-2017* | 29-May-2018* | 3 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Amora, a female Rottweiler of 1 year old and 38 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS L (FL) (012/16 and unknown exp date, topical, btw the shoulder blades), applied by the reporter 3 weeks ago (8 May 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jul 2017 chosen at random). There are two more dogs in this household with the same issue (see cases 18BR004023 and 18BR004025). No further information is expected. |
| 29-May-2018 | UAE; 18BR004025; SC; Brazil | **Species:** Canine<br>**Breed:** Border Collie<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Month(s)<br>**Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Dec-2017* | 29-May-2018* | 3 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Cacau, a female Border Collie of 9 months old and 15 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS M (FL) (011/16 and unknown exp date, topical, btw the shoulder blades), applied by the reporter 3 weeks ago (8 May 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Dec 2017 chosen at random). There are two more dogs in this household with the same issue (see cases 18BR004023 and 18BR004024). No further information is expected. |
| 27-May-2018 | UAE; 18BR004026; ES; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the** | N/A | 20-May-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via social media, his dog was treated with FRONTLINE, but continued to have fleas. UPDATE 29 MAY 2018 – Tizy, a 2-year-old, 6 kg, female, crossbred dog, was treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, not on whole body (dog did not got wet post FL application), by the reporter, on date not specified (20 May 2018 chosen at random), for flea treatment treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation 3 days prior to FL, |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **product used ok?:** No (Treatment / vaccination program not respected) | | | | | environment treated (details not provided). It is unknown if FRONTLINE was applied to Tizy in the past. No further information is available. |
| 29-May-2018 | UAE; 18BR004035; SP; Brazil | **Species:** Canine **Breed:** Pug **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 11 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 28-May-2018* | 23 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Buzz, 3 years old, 11 kilogram, canine, male, Pug, received FRONTLINE PLUS DOG M (lot, exp date, topically, between the shoulder blades), applied by the reporter on 5 May 2018 for tick control. The owner complained about the lack of efficacy of FL because she found a tick yesterday (29 May 2018) on her animal. The environment has been treated 1 month ago because the animal was previously, presenting fleas. It is unknown if the animal already received FL in the past. No further information is avaiable. |
| 30-May-2018 | UAE; 18BR004042; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mia, a 7-month-old, 4.5 kg, female mixed breeds cat, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 15 days ago (15 May 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 1 month prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the cat in the past. No further information is available. |
| 30-May-2018 | UAE; 18BR004044; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 30-May-2018* | 11 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sofia, 2 years old, 2 kilogram, feline, female, Mixed Breed, received FRONTLINE PLUS CATS (lot, exp date, topically, between the shoulder blades), applied by the reporter on 19 May 2018 for flea treatment. The owner complained about the lack of efficacy of FL because she continues to see fleas in her cat. According to the owner, animal already had fleas 4 days prior to treatment. The environment has not been treated. It is unknown if the animal already received FL in the past. No further information is available. |
| 30-May-2018 | UAE; 18BR004045; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 27-Mar-2018 | 27-Mar-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Aladim, a male Yorkshire of 4 months old and 1.5 kg, was treated with FRONTLINE SPRAY (FL) (001/17, Dec 2018, topical, whole body), applied by the reporter, starting 2 months ago (27 Mar 2018), every 15 days, last dose on 26 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 30-May-2018 | UAE; 18BR004046; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 30-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Tuluzi, a male mixed breed cat of 2 years old and 4.5 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 28 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases reported on 18BR004047, 18BR004048 and 18BR004049. No further information is expected. |
| 30-May-2018 | UAE; 18BR004047; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 30-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Catarina, a female mixed breed cat of 4 years old and 2.5 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 28 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases reported on 18BR004046, 18BR004048 and 18BR004049. No further information is expected. |
| 30-May-2018 | UAE; 18BR004048; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 30-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Marry, a female mixed breed cat of 3 years old and 3 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 28 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases reported on 18BR004046, 18BR004047 and 18BR004049. No further information is expected. |
| 30-May-2018 | UAE; 18BR004049; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 13.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 30-May-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mili, a female medium crossbred dog of 4 years old and 13.5 kg, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 28 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases reported on 18BR004046, 18BR004047 and 18BR004048. No further information is expected. |
| 28-May-2018 | UAE; 18BR004050; PR; Brazil | **Species:** Canine **Breed:** Small | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG | N/A | 26-May-2018* | 0 Day(s) | D-C | Suspected Adverse Event: As reported by the referral veterinarian, Nina, 8 months old, 6 kilogram, canine, female, Mixed Breed, received FRONTLINE SPOT-ON DOGS S. (FL) (lot, exp date, |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Month(s)<br>**Weight:** 6 kg | | | | **Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | route and site of administration unknown). applied by the owner on saturday (26 May 2018 – estimated date), for unknown reason. On the same day the animal presented paralysis, tremors, hypersalivation, dyspnoea and red lips. The animal temperate was 38.5 degrees celsius. It is unknown if the animal received any treatment or if FL was applied in the past. The current health state of Nina is unknown. No further information is available. |
| 30-May-2018 | UAE; 18BR004054; RJ; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 19.00 Month(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 30-May-2018* | 4 Week(s) 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Fofinha, a male Yorkshire of 19 months old and 3 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 26 Apr 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied . No further information is expected. |
| 29-May-2018 | UAE; 18BR004059; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 5.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-May-2018* | 20-May-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Shih Tzu of 1 year old and 5.6 kg, was treated, for the second time, with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 16 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has been treated with deltamethrin and amitraz. FL was applied for the first time around 1 May 2018, but the animal also had fleas. No further information is expected. |
| 30-May-2018 | UAE; 18BR004060; SP; Brazil | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 20 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 30-May-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, an unidentified dog, 3 years old, 20 kilogram, canine, male, Mixed Breed, received FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner on Thursday (24 May 2018 – estimated date), for flea and tick treatment. The owner complained that the product did not kill the fleas, only the ticks. According to the owner, animal already had fleas 1 week prior to administration. The environment has been treated with BUTOX®. It is unknown if the animal already received FL in the past. No further information is available. |
| 30-May-2018 | UAE; 18BR004064; SP; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 5.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous | 10-Apr-2016* | 11-Apr-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the owner, Thor, 3 years old, 5.1 kilograms, canine, male, Lhasa Apso, received FRONTLINE PLUS DOG S (FL) (lot 014/17, exp date unknown, topically, between the shoulder blades ), applied by the owner on 10 Apr 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Then, another vial of FL was applied to the dog on 21 May 2018 and it has worked. Thor is not infested by fleas anymore. According to the owner, FRONTLINE was usually applied every 3 months with no issues (10 Apr 2016 chosen at random for first application). The |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **Was the product used ok?:** Yes | | | | | environment is treated once a year with an unidentified product. No further information is available. |
| 31-May-2018 | UAE; 18BR004065; MG; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2016* | 31-May-2018* | 30 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Estrela, a female Poodle of 15 years old and 4 kg, received one dose of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 18 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has been treated with deltamethrin. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2016 chosen at random). No further information is expected. |
| 01-Jun-2018 | UAE; 18BR004066; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 12 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 01-Jun-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Jade, a female medium crossbred dog of 6 years old and 12 kg, received one vial of FRONTLINE PLUS DOG M (FL) (009/16, Nov 2018, topical, btw the shoulder blades), applied by the reporter on 21 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied . No further information is expected. |
| 04-Jun-2018 | UAE; 18BR004082; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 20.00 Year(s) **Weight:** 4.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 21-Jan-2017* | 04-Jun-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Théo, a male mixed breed cat of 20 years old and 4.8 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (004/17, Feb 2019, topical, btw the shoulder blades), applied by the reporter on 21 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL has been applied every 3 months with no issue since date not specified (21 Jan 2017 - chosen at random). No further information is expected. |
| 04-Jun-2018 | UAE; 18BR004085; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 4.4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 15-May-2016* | 15-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the owner: Helena, 5 year old, 4.4 kilograms, canine, female, Yorkshire, received, a dose of FRONTLINE PLUS DOG S (FL) (lot, exp date, route and site of administration unknown), applied by the owner on 15 May 2018. for flea and tick control. According to the owner, the animal bit her while she had the pipette in her hand and the owner believes Helena ingested a portion of FL content . According to the owner the animal presented on the same day movements with the tongue that lasted from 5 to 10 minutes. After drink water the animal recovered. The animal presented hypersalivation and movements with the tongue by the end of the next day and then recovered. On friday (18 May 2018 – estimated date), the animal present the same reaction twice. The animal was taken to the veterinarian who examined and said the animal was well. During the saturday (19 May 2018 – estimated date) the animal presented |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)
* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | the same problem again and the owner recorded the event and sent to the DVM. Helena was hospitalized and treated with diazepam, propofol, and GARDENAL®. The animal returned home in an unspecified date and on tuesday (19 May 2018 – estimated date), presented the symptoms again, lasting until 27 May 2018. A tomography and a neurological evaluation were performed without any differential diagnosis. The owner already used FL in the past with no issues (15 May 2016 – date chosen at random). No further information is available. |
| 04-Jun-2018 | UAE; 18BR004088; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 5.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 02-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nelsinho, an 18-month-old, 5.5 kg, male mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, location unknown, by the reporter, on 1 Jun 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation one month prior to FL, environment treated. It is unknown if FRONTLINE was applied to the cat in the past. No further information is available. |
| 04-Jun-2018 | UAE; 18BR004089; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 27-Mar-2018* | 02-Jun-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Florzinha, a female mixed breed cat of 2 years old and 4 kg, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (lot, exp date, route and location are unknown), applied by the reporter around 27 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was also applied around 2 months ago with no issue. A similar case was reported on 18BR004090. There is one dog in this household that was treated with another product, but the details are unknown. No further information is expected. |
| 04-Jun-2018 | UAE; 18BR004090; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 27-Mar-2018* | 02-Jun-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female mixed breed cat of 7 years old and 4 kg, was treated with one vial of FRONTLINE SPOT-ON CATS (FL) (lot, exp date, route and location are unknown), applied by the reporter around 27 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was also applied around 2 months ago (27 Mar 2018). A similar case was reported on 18BR004089. There is a dog in this household that was treated with another product, but the details are unknown. No further information is expected. |
| 04-Jun-2018 | UAE; 18BR004092; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 1.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous | N/A | 04-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bidu, a male Yorkshire of 3 years old and 1.8 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 15 days ago (20 May 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (See case 18BR004093). No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **Was the product used ok?:** Yes | | | | | |
| 04-Jun-2018 | UAE; 18BR004093; SP; Brazil | **Species:** Canine **Breed:** Maltese **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 04-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Ozzi, a male Maltese of 6 years old and 5 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 15 days ago (20 May 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (See case 18BR004092). No further information is expected. |
| 03-Jun-2018 | UAE; 18BR004095; PR; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, one Yorkshire Terrier of unknown signalment was treated with one vial of FRONTLINE PLUS DOGS, by the reporter, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. UPDATE 5 MAY 2018 – Johnnie, a 3-year-old, 7 kg, male Yorkie, was treated with FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades. Tick infestation prior to FL, environment was treated with amitraz. It is unknown if FRONTLINE was applied to the dog in the past. There is one other dog in the same household that is also on FRONTLINE and was reported on 18BR004096. No further information is available. |
| 03-Jun-2018 | UAE; 18BR004096; PR; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Month(s) **Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 16-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, one female dog of unknown signalment was treated with one vial of FRONTLINE SPOT-ON DOG, by the reporter, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. UPDATE 5 MAY 2018 – Aika, a 12-month-old, 15 kg, female, crossbred dog, was treated with FRONTLINE SPOT-ON DOGS M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades. Tick infestation prior to FL, environment was treated with amitraz. It is unknown if FRONTLINE was applied to the dog in the past. There is one other dog in the same household that is also on FRONTLINE and was reported on 18BR004095. No further information is available. |
| 02-Jun-2018 | UAE; 18BR004103; SP; Brazil | **Species:** Canine **Breed:** Beagle **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 24.3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Jan-2017* | 02-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, Jack, a male Beagle of 8 years old and 24.3 kg, was treated with one vial of FRONTLINE PLUS DOG L (FL) (lot, exp date, route and location are unknown), applied by the vet on 1 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet had fleas. Jack has flea allergy dermatitis and he has no outdoor access. The environment has been treated with deltamethrin and FL has been applied every 3 months since date not specified (1 Jan 2017 - chosen at random). Another product against fleas was applied and the pet is currently free of ectoparasites. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 05-Jun-2018 | UAE; 18BR004106; RJ; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 30-May-2018 | 30-May-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, FRONTLINE SPRAY (FL) (017/16, Nov 2018) was applied to her pets, but the product did not work. UPDATE 5 JUN 2018 – Tatazinha, an 8-year-old, 2 kg, female, Poodle, was treated with FL, topic, 'back and belly', by the reporter, for the first time, on 30 May 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation one month prior to FL, environment treated (details not provided). FRONTLINE 'pipette' was usually applied every 2 months with no issues. There are 2 other dogs in the same household, but only one was treated with FL and experienced the same issues (see 18BR004107). No further information is available. |
| 05-Jun-2018 | UAE; 18BR004107; RJ; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 30-May-2018 | 30-May-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, FRONTLINE SPRAY (FL) (017/16, Nov 2018) was applied to her pets, but the product did not work. UPDATE 5 JUN 2018 – Penelope, a 2-year-old, 4 kg, female, Poodle, was treated with FL, topic, 'back and belly', by the reporter, for the first time, on 30 May 2018, for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation one month prior to FL, environment treated (details not provided). FRONTLINE 'pipette' was usually applied every 2 months with no issues. There are 2 other dogs in the same household, but only one was treated with FL and experienced the same issues (see 18BR004106). No further information is available. |
| 05-Jun-2018 | UAE; 18BR004109; SP; Brazil | **Species:** Canine **Breed:** Basset Hound **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 8.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 17-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Fiona, a 14-year-old, 8.5 kg, female, Basset Hound, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 20 days ago (16 May 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas . Flea infestation one month prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 05-Jun-2018 | UAE; 18BR004110; RJ; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** U **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 17 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 03-Feb-2018* | 20-Apr-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Marcos, 2 years old, 17 kilograms, canine, Mixed Breed, received one pipette of FRONTLINE PLUS DOG M (FL) (lot 009/16 and exp date NOV 2018), topically, between the shoulder blades ), by the reporter, on 3 June 2018, for flea and tick treatment. The owner complaint that his animal remained with live ticks. According to the owner, his animal already had ticks 3 months prior to FL use. The animal already received FL in the past (3 Feb 2018 – date chosen at random). The owner, prior to 3 June 2018, had already used FL for three times, 1 pipette each time, with 15 to 20 days interval between them without results. The owner also said that after the last application, after returning home from a walk on the streets, the animal had many ticks on him. The environment is not treated. No further information is available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 06-Jun-2018 | UAE; 18BR004115; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 06-Jun-2018 | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Zizio, unknown age, unknown weight, male, Feline, Mixed Breed, was treated with FRONTLINE SPRAY (FL) (004/17, exp date unknown, topically, in the whole body) by the reporter, 15 days ago (22 May 2018 – estimated date). The owner complained about the lack of efficacy, because her animal continues with fleas. According to the owner, animal already had fleas 20 days prior to treatment. The owner said that the animal does not leave the house. The environment has been treated with KOCIDE® and BUTOX®. There are another 6 cats in the same household with similar problem (see cases 18BR004116 to 18BR004121). It is unknown if the animal already received FL in the past. No further information is available. |
| 06-Jun-2018 | UAE; 18BR004116; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 06-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Vitoria, unknown age, unknown weight, female, Feline, Mixed Breed, was treated with FRONTLINE SPRAY (FL) (004/17, exp date unknown, topically, in the whole body) by the reporter, 15 days ago (22 May 2018 – estimated date). The owner complained about the lack of efficacy, because her animal continues with fleas. According to the owner, animal already had fleas 20 days prior to treatment. The owner said that the animal does not leave the house. The environment has been treated with KOCIDE® and BUTOX®. There are another 6 cats in the same household with similar problem (see cases 18BR004115 and 18BR004117 to 18BR004121). It is unknown if the animal already received FL in the past. No further information is available. |
| 06-Jun-2018 | UAE; 18BR004117; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 06-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Vitor, unknown age, unknown weight, male, Feline, Mixed Breed, was treated with FRONTLINE SPRAY (FL) (004/17, exp date unknown, topically, in the whole body) by the reporter, 15 days ago (22 May 2018 – estimated date). The owner complained about the lack of efficacy, because her animal continues with fleas. According to the owner, animal already had fleas 20 days prior to treatment. The owner said that the animal does not leave the house. The environment has been treated with KOCIDE® and BUTOX®. There are another 6 cats in the same household with similar problem (see cases 18BR004115, 18BR004116 and 18BR004118 to 18BR004121). It is unknown if the animal already received FL in the past. No further information is available. |
| 06-Jun-2018 | UAE; 18BR004118; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 06-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Vandinha, 1 year old, unknown weight, female, Feline, Mixed Breed, was treated with FRONTLINE SPRAY (FL) (004/17, exp date unknown, topically, in the whole body) by the reporter, 15 days ago (22 May 2018 – estimated date). The owner complained about the lack of efficacy, because her animal continues with fleas. According to the owner, animal already had fleas 20 days prior to treatment. The owner said that the animal does not leave the house. The environment has been treated with KOCIDE® and BUTOX®. There are another 6 cats in the same household with similar problem (see cases 18BR004115, 18BR004116, 18BR004117 and 18BR004119 to 18BR004121). It is unknown if the animal already received FL in the past. No further information is available. |
| 06-Jun-2018 | UAE; 18BR004119; | **Species:** Feline **Breed:** Feline | 1 | 1 | 0 | **Product used:** FIPRONIL | N/A | 06-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Vivi, unknown age, unknown weight, female, Feline, Mixed Breed, |

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| | SP; Brazil | mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | was treated with FRONTLINE SPRAY (FL) (004/17, exp date unknown, topically, in the whole body) by the reporter, 15 days ago (22 May 2018 – estimated date). The owner complained about the lack of efficacy, because her animal continues with fleas. According to the owner, animal already had fleas 20 days prior to treatment. The owner said that the animal does not leave the house. The environment has been treated with KOCIDE® and BUTOX®. There are another 6 cats in the same household with similar problem (see cases 18BR004115 to 18BR004118, 18BR004120 and 18BR004121). It is unknown if the animal already received FL in the past. No further information is available. |
| 06-Jun-2018 | UAE; 18BR004120; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 06-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Vilma, 1 year old, unknown weight, female, Feline, Mixed Breed, was treated with FRONTLINE SPRAY (FL) (004/17, exp date unknown, topically, in the whole body) by the reporter, 15 days ago (22 May 2018 – estimated date). The owner complained about the lack of efficacy, because her animal continues with fleas. According to the owner, animal already had fleas 20 days prior to treatment. The owner said that the animal does not leave the house. The environment has been treated with KOCIDE® and BUTOX®. There are another 6 cats in the same household with similar problem (see cases 18BR004115 to 18BR004119 and 18BR004121). It is unknown if the animal already received FL in the past. No further information is available. |
| 06-Jun-2018 | UAE; 18BR004121; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 06-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Val, unknown age, unknown weight, female, Feline, Mixed Breed, was treated with FRONTLINE SPRAY (FL) (004/17, exp date unknown, topically, in the whole body) by the reporter, 15 days ago (22 May 2018 – estimated date). The owner complained about the lack of efficacy, because her animal continues with fleas. According to the owner, animal already had fleas 20 days prior to treatment. The owner said that the animal does not leave the house. The environment has been treated with KOCIDE® and BUTOX®. There are another 6 cats in the same household with similar problem (see cases 18BR004115 to 18BR004120). It is unknown if the animal already received FL in the past. No further information is available. |
| 06-Jun-2018 | UAE; 18BR004130; PR; Brazil | **Species:** Canine<br>**Breed:** English Bulldog<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Month(s)<br>**Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 03-Jun-2018* | 1 Week(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Mauí, an 8-month-old, 14 kg, male, English Bulldog, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), 'according to the product label' (topic, between the shoulder blades), by the reporter, 10 days ago (27 May 2018), for flea treatment. Mauí was in good health prior to FL. 1 week post product application, the owner noticed hair loss, reddening of the skin and itching, all signs at the application site. Mauí was taken to the vet clinic on date not specified. The attending vet was contacted and she confirmed the signs reported by the owner. Dermotrat and Omega 3 and 5 were prescribed for treatment. The signs are still ongoing, however it is unknown if Mauí is under treatment. There is no further information expected. |
| 07-Jun-2018 | UAE; 18BR004147; RJ; Brazil | **Species:** Canine<br>**Breed:** Pit Bull<br>**Sex:** F<br>**Sex qualifier:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | 25-May-2018 | 07-Jun-2018* | 20 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown, 12 kilograms, female, canine, Pit Bull, received one pipette of FRONTLINE PLUS DOGS ® (FL) (size, lot, exp date, route and site of administration unknown), by an unspecified person, around 3 weeks ago (18 May 2018 – estimated date), for |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Age:** 8.00 Month(s)<br>**Weight:** 12 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | flea treatment. The owner complained that her animal remained with fleas. The owner lives in an apartment and the dog does not go out on the streets. It is unknown if the animal already received FL in the past. No further information is available. UPDATE 11 JUN 12018 – Moana, 8 months old, was treated with one vial of FL, topic, base of skull and btw the shoulder blades, by the reporter, for the first time, on 25 May 2018. Flea infestation prior to FL, environment treated with Butox, outdoor access denied. There is no further information expected. |
| 08-Jun-2018 | UAE; 18BR004148; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 06-Jun-2018 | 06-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Nina, a 12-year-old, 4 kg, female, mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, between the shoulder blades, by the reporter, for the first time, on 6 Jun 2018, for flea and tick prevention. She was in good health prior to FL and has no history of adverse reactions. Few hours post product application (end of the day), the cat started experiencing hair loss at the application site. Yesterday (7 Jun 2018), the application site had no hair anymore. Other signs denied. Nina was not taken to the vet clinic. There is no further information expected. |
| 08-Jun-2018 | UAE; 18BR004150; PR; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 11.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 08-Jun-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner (who is also a vet), Peg, a female Lhasa Apso of 11 years old and 6 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 5 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with Butox® and it is unknown if FL has previously been applied. The pet has no outdoor access. There is another dog in this household with the same issue (see case 18BR004151). No further information is expected. UPDATE 13 JUN 2018 - FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). The dog was also bathed with a shampoo against fleas and another vial of FL was applied on date not specified (9 Jun 2018 - chosen at random), but the product was fractioned. The pet remains infested. No further information is expected. |
| 08-Jun-2018 | UAE; 18BR004151; PR; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 14.00 Year(s)<br>**Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not | 01-Jan-2017* | 08-Jun-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Meg, a female Yorkshire of 14 years old and 3.5 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 5 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with Butox® and it is unknown if FL has previously been applied. The pet has no outdoor access. There is another dog in this household with the same issue (see case 18BR004150). No further information is expected. UPDATE 13 JUN 2018 - FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). The dog was also bathed with a shampoo against fleas and another vial of FL was applied on date not specified (9 Jun 2018 - chosen at random), but the product was fractioned. The pet remains infested. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | respected) | | | | | |
| 08-Jun-2018 | UAE; 18BR004153; BA; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2016* | 31-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Cleo, a 13-year-old, 4 kg, female, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (001/17, exp unknown), topic, whole body, by the reporter, on 31 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. As FL did not work, the product was applied again today (8 Jun 2018), but Cleo is still infested by fleas. Flea infestation few days prior to FL, environment not treated. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2016 chosen at random). 2 other cats of the same household that are also on FL were reported on 18BR004154 and 18BR004155. No further information is available. |
| 08-Jun-2018 | UAE; 18BR004154; BA; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2016* | 31-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a 4-year-old, 5 kg, female, mixed breed cat, was treated with FRONTLINE SPRAY (FL) (001/17, exp unknown), topic, whole body, by the reporter, on 31 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas . As FL did not work, the product was applied again today (8 Jun 2018), but Nina is still infested by fleas. Flea infestation few days prior to FL, environment not treated. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2016 chosen at random). 2 other cats of the same household that are also on FL were reported on 18BR004153 and 18BR004155. No further information is available. |
| 08-Jun-2018 | UAE; 18BR004155; BA; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 31-May-2018 | 31-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a 2-month-old, 1 kg, female, mixed breed cat, recently rescued, was treated with FRONTLINE SPRAY (FL) (001/17, exp unknown), topic, whole body, by the reporter, on 31 May 2018, for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. As FL did not work, the product was applied again today (8 Jun 2018), but Belinha is still infested by fleas. Flea infestation few days prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the kitten in the past. 2 other cats of the same household that are also on FL were reported on 18BR004153 and 18BR004154. No further information is available. |
| 08-Jun-2018 | UAE; 18BR004156; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 18.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the** | N/A | 08-Jun-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Nina, a female Poodle of 18 years old and 8 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 4 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **product used ok?:** Yes | | | | | |
| 08-Jun-2018 | UAE; 18BR004157; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 0.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 08-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, one 2-month-old, 0.6 kg, male, Yorkshire Terrier, was treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, whole body, by the reporter, this morning (8 Jun 2018), for flea treatment. She discovered dead fleas, however lack of efficacy suspected because the pup continued to have live fleas. Flea infestation prior to FL, environment treated. It is unknown if FRONTLINE was applied to the dog in the past. Similar case reported on 18BR004158. No further information is available. |
| 08-Jun-2018 | UAE; 18BR004158; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Month(s) **Weight:** 0.6 kg | 3 | 3 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 08-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, three 2-month-old, 0.6 kg, female, Yorkshire Terrier, were treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, whole body, by the reporter, this morning (8 Jun 2018), for flea treatment. She discovered dead fleas, however lack of efficacy suspected because the puppies continued to have live fleas. Flea infestation prior to FL, environment treated. It is unknown if FRONTLINE was applied to the dog in the past. Similar case reported on 18BR004157. No further information is available. |
| 07-Jun-2018 | UAE; 18BR004160; -; Brazil | **Species:** Canine **Breed:** Fox Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 19 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 31-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown, 19 kilograms, male, canine, received one pipette of FRONTLINE TRI-ACT 20-40 Kg (FL) (lot, exp date, route and site of administration unknown), applied by the owner on an unspecified date (30 May 2018 – date chosen at random), for tick treatment. The owner complained that he continues to see ticks in his dog. According to the owner, he already had the same problem months ago (20 Dec 2017 – date chosen at random) with FRONTLINE PLUS® (see cases 18BR004161 and 18BR004162), but as he was used to apply the product without issues, he ignored the situation. The owner said that he always applied the product as per label recommendation topically , between the shoulder blades) and that he also shaves the region prior to application. There is another dog in the same household with similar problem (see case 18BR004159). No further information is available. UPDATE 11 JUN 2018 - The pet owner was contacted and she reported that July, a 2-year-old, female, Fox Terrier, was treated with one vial of FRONTLINE SPOT-ON DOGS L (FL), on 30 May 2018. Tick infestation one week prior to FL, environment treated with Butox. She is not infested by ticks anymore, only the other dog of the same household continued to have ticks post FRONTLINE TRI-ACT 20-40 KG (case 18BR004159). No further information is available. |
| 07-Jun-2018 | UAE; 18BR004161; RJ; Brazil | **Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products | N/A | 01-Jan-2017* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown, 21 kilograms, male, canine, received a dose of FRONTLINE PLUS® (FL) (lot, exp date, route and site of administration unknown), applied by an unknown person, on an unspecified date (20 Dec 2017 – date chosen at random), for tick treatment. The owner complained that after FL application he continued to see ticks in his dogs. According to the owner, he already used FL in the past without issues (20 Feb 2017 – date |

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| | | | | | | **Route:** unknown **Was the product used ok?:** Unknown to Company | | | | | chosen at random). There is another dog in the same household who had a similar problem (see case 18BR004162). The owner also used FRONTLINE TRI-ACT 20-40 Kg months after and had the same issues (see cases 18BR004159 and 18BR004160). The environmental conditions are unknown. No further information is available. UPDATE 11 JUN 2018 - The pet owner was contacted and he confirmed that an unknown number of Pinschers of unknown signalment were usually treated with FRONTLINE PLUS DOGS in the past (date not specified - 1 Jan 2017 chosen at random), but the product did not work. Details were not provided, since he is not the owner (his father is). There is no further information expected. |
| 08-Jun-2018 | UAE; 18BR004163; PR; Brazil | **Species:** Canine **Breed:** Pekingese **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 6.5 kg | 2 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 08-Jun-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Jerry, a male Pekingese of 2 years old and 6.5 kg, was treated with FRONTLINE SPRAY (FL) (003/17, Jan 2019, topical, parts of the body - incorrect application), applied by the reporter on 3 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment was treated on February of 2018. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). There is another dog in this household that was also treated with FL and it has no issue. No further information is expected. |
| 08-Jun-2018 | UAE; 18BR004167; -; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 05-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown, canine, received a dose of FRONTLINE® (FL) (lot, exp date, route and site of administration unknown), applied by the owner, on an unspecified date (5 Jun 2018 – date chosen at random), for flea treatment. The owner complained that she continues to see fleas, alive, in her animal. The environmental conditions are unknown. It is unknown if the animal already had FL in the past. No further information is available. |
| 11-Jun-2018 | UAE; 18BR004174; PB; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 8.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 11-Mar-2018* | 11-Jun-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Magali, 10 years old, 8.8 kilograms, canine, female, Shih Tzu, received 1 pipette of FRONTLINE PLUS DOG S (FL) (lot 018/17 and exp date unknown, topically, between the shoulder blades ), applied by the owner, 1 month ago (11 May 2018 – estimated date), for flea and tick treatment. The owner complained that 3 months ago (11 Mar 2018 - estimated date) she applied FL and after 1 week the fleas returned to her animal, now, after the last application the animal continued with fleas. According to the owner , animal already had parasites 2 months prior to the last application. The environment has not been treated. No further information is available. |
| 11-Jun-2018 | UAE; 18BR004180; | **Species:** Feline **Breed:** Turkish | 1 | 1 | 0 | **Product used:** FIPRONIL | N/A | 10-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Luna, 9 months old, 2.5 kilograms, Feline, female, Turkish Angora, |

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| | SP; Brazil | Angora<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Month(s)<br>**Weight:** 2.5 kg | | | | SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | received an unknown dose of FRONTLINE SPRAY® (FL) (lot 018/16 and exp date unknown, topically, in parts of the body ), applied by the owner on 10 Jun 2018, around 7 p.m. for flea treatment. The owner complained that she continues to see live fleas in her pet. According to the owner, animal already had fleas 1 month and a half prior to FL application. The environment has been treated with K-OTHRINE®. The owner is uncertain if FL was applied in the entire animal´s body. There are another 2 cats in the same household with a similar problem (see cases 18BR004181 and 18BR004182). It is unknown if FL was used in the past. No further information is available. |
| 11-Jun-2018 | UAE; 18BR004181; SP; Brazil | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 20.00 Day(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 10-Jun-2018 | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, a unidentified , feline, male, 20 days old, unknown weight, received an unknown dose of FRONTLINE SPRAY® (FL) (lot 018/16 and exp date unknown, topically, in parts of the body ), applied by the owner on 10 Jun 2018, around 7 p.m. for flea treatment. The owner complained that she continues to see live fleas in her pet. The environment has been treated with K-OTHRINE®. The owner is uncertain if FL was applied in the entire animal´s body. There are another 2 cats in the same household with a similar problem (see cases 18BR004180 and 18BR004182). It is unknown if FL was used in the past. No further information is available. |
| 11-Jun-2018 | UAE; 18BR004182; SP; Brazil | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 20.00 Day(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 10-Jun-2018 | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, a unidentified , feline, female, 20 days old, unknown weight, received an unknown dose of FRONTLINE SPRAY® (FL) (lot 018/16 and exp date unknown, topically, in parts of the body ), applied by the owner on 10 Jun 2018, around 7 p.m. for flea treatment. The owner complained that she continues to see live fleas in her pet. The environment has been treated with K-OTHRINE®. The owner is uncertain if FL was applied in the entire animal´s body. There are another 2 cats in the same household with a similar problem (see cases 18BR004180 and 18BR004181). It is unknown if FL was used in the past. No further information is available. |
| 12-Jun-2018 | UAE; 18BR004189; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 3.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 10-Jun-2018* | 3 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Princesa, a female Yorkshire of 5 years old and 3.8 kg, was treated with one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 20 May 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with ectoparasites. The environment has been treated with deltamethrin every 2 months. FL has been applied monthly since date not specified (1 Jan 2017 - chosen at random). There is another dog in this household, but it is unknown if it was treated. No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 12-Jun-2018 | UAE; 18BR004191; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 12-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pipo, a male mixed breed cat of 2 years old and 3 kg, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 15 days ago (28 May 2018), for flea control. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. No further information is expected. |
| 11-Jun-2018 | UAE; 18BR004194; RJ; Brazil | **Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 16.00 Year(s) **Weight:** 2.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** occlusive dressing technique **Was the product used ok?:** Yes | 07-Jun-2018 | 12-Jun-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Latiça, a female Pinscher of 16 years old and 2.8 k, was treated, for the first time, with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 7 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. No further information is expected. |
| 12-Jun-2018 | UAE; 18BR004196; SP; Brazil | **Species:** Canine **Breed:** French Bulldog **Sex:** M **Sex qualifier:** - **Age:** 27.00 Month(s) **Weight:** 11 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 10-Jun-2017* | 12-Jun-2018* | 2 Day(s) | D-C | Suspected Adverse Event: As reported by the veterinarian via distributor, Toreto, an intact male French Bulldog of 27 months old and 11 kg, was treated with one vial of FRONTLINE PLUS (FL) (unsubstantiated) (lot and exp date are unknown), topical, between the shoulder blades, applied by the reporter on date not specified, for flea/tick control. The dog was in good health prior to FL and has no history of adverse reactions. After product application, Toreto presented with agitation and discomfort. A wound was developed at the application site. The application site is swelling and has a bad odor. The pet also presented with vomiting. At the clinical examination, the pet was panting. In addition, the vet has identified a purulent and erythematous skin lesion (approximately 6 cm in diameter) at the application site. No other changes were presented. The vet suspected of pharmacodermia related to FL. The pet was treated with dexamethasone, Agemoxi®, dipyrone and Cerenia®. The vet also prescribed cephalexin, Vonau®, prednisolone and Lactobac®. The current status of the animal is unknown. FL was applied in the past with no issue (1 Jan 2018 - chosen at random). No further information is available. UPDATE 13 JUN 2018 – The DVM was contacted and does not know which FRONTLINE® was applied in the animal. The DVM believes FL was applied 2 to 3 days ago (10 Jun 2018 – estimated date). The animal also presented loose stools (12 Jun 2018 - estimated date). During the return to the clinic, the lesion size has decreased. No further information is available. UPDATE 14 JUN 2018 – The owner was contacted and informed the pipette was green (FRONTLINE PLUS, unsubstantiated). The animal was in good health previous to application and the owner already used FL for 1 year (10 Jun 2017 – estimated date). The animal recovered but the hair still hadn't grow on the spot. No further information is available. UPDATE 26 JUN 2018 - According to the retail store |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | staff member, the product applied on |
| 13-Jun-2018 | UAE; 18BR004198; GO; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.10 Year(s) **Weight:** 9.3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 07-Jun-2018 | 13-Jun-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a female small crossbred dog of 5.1 years old and 9.3 kg, was treated, for the first time, with FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 7 Jun 2018, for tick control. Lack of efficacy is suspected because live ticks were found on the dog today (13 Jun 2018). The environment has been treated with cypermethrin. No further information is expected. UPDATE 14 JUN 2018 – The owner contacted again and said that her animal continues infested by ticks and that Belinha already had tick borne disease in the past. No further information is available. |
| 13-Jun-2018 | UAE; 18BR004202; DF; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 23 kg | 4 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 30-May-2018 | 13-Jun-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Otto, a male large crossbred dog of 14 years old and 23 kg, was treated, for the first time, with FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 30 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has not been treated. There are 3 more dogs in this household that were treated with FL and they have no issue . No further information is expected. |
| 13-Jun-2018 | UAE; 18BR004206; PR; Brazil | **Species:** Feline **Breed:** Siamese **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 13-Jun-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bebe, unknown age, 4 kilograms, feline, male, Siamese, received 1 pipette of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner on 30 May 2018, for flea treatment. The owner complained that she continues to see fleas in her pet. According to the owner, animal already had parasites 1 month and a half prior to the application. The environment has not been treated. There is another cat in the same household with a similar problem (see case 18BR004207). It is unknown if the animal already received FL in the past. No further information is available. |
| 13-Jun-2018 | UAE; 18BR004207; PR; Brazil | **Species:** Feline **Breed:** Siamese **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 13-Jun-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bola, unknown age, 4 kilograms, feline, male, Siamese, received 1 pipette of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner on 30 May 2018, for flea treatment. The owner complained that she continues to see fleas in her pet. According to the owner, animal already had parasites 1 month and a half prior to the application. The environment has not been treated. There is another cat in the same household with a similar problem (see case 18BR004206). It is unknown if the animal already received FL in the past. No further information is available. |

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| 13-Jun-2018 | UAE; 18BR004209; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 02-Jun-2018* | 20 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dudu, a male Yorkshire of 6 years old and 2 kg, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter one month ago (13 May 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. There are 2 more dogs in this household with the same issue (see cases 18BR004210 and 18BR004211). No further information is expected. |
| 13-Jun-2018 | UAE; 18BR004210; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 05-Jun-2018* | 23 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Neguinho, a male small crossbred dog of 10 years old and 6 kg, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter one month ago (13 May 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. There are 2 more dogs in this household with the same issue (see cases 18BR004209 and 18BR004211). No further information is expected. |
| 13-Jun-2018 | UAE; 18BR004211; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 02-Jun-2018* | 20 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lili, a female Poodle of 10 years old and 3 kg, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter one month ago (13 May 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. There are 2 more dogs in this household with the same issue (see cases 18BR004209 and 18BR004210). No further information is expected. |
| 13-Jun-2018 | UAE; 18BR004212; -; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 05-Oct-2003* | 06-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Meli, 15 years old, 4 kilograms, canine, female, Lhasa Apso, received 1 pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner on 5 May 2018, for flea treatment. The owner complained that it has been a month since her dog is infested by fleas (13 May 2018 - estimated date). According to the owner, the fleas initially died but then, new ones appeared. The environment has been treated twice with K-othrine and Pulgoff. There is also another dog in the same household with similar problem (see case 18BR004213). She has been using FL for 16 years (5 Oct 2003 – date chosen at random) and she only had a similar problem once with an unidentified patient (date not specified). The animal does not leave the house for walks. No further information is available. UPDATE 19 JUN 2018 – The owner contacted and according to her there was an application of FL in December (10 Dec 2017 – date chosen at random) and by that time she also had another dog in her house (the owner did not specify if this dog received FL) and believe that this dog was responsible for the others to have fleas. According to the owner 20 days after the application (30 Dec 2017 – date chosen at random) her animal presented fleas again. The owner treated the environment and on 5 May 2018 she applied FL |

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| | | | | | | | | | | | again but without results. The dog sleeps in blankets and the owner applied Pulgoff on these blankets. Last week the owner used FRONTLINE PLUS ® and the animal recovered from flea infestation. The animal does not leave the house. No further information is available. |
| 13-Jun-2018 | UAE; 18BR004213; -; Brazil | **Species:** Canine **Breed:** Japanese Chin **Sex:** F **Sex qualifier:** Unknown **Age:** 13.00 Year(s) **Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 05-Oct-2005* | 06-May-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Penelope, 13 years old, 3.5 kilograms, canine, female, Japanese Chin Dog, received 1 pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 5 May 2018, for flea treatment. The owner complained that it has been a month since her dog is infested by fleas (13 May 2018 - estimated date). According to the owner, the fleas initially died but then, new ones appeared. The environment has been treated twice with K-othrine and Pulgoff. There is also another dog in the same household with similar problem (see case 18BR004212). She has been using FL for 16 years (5 Oct 2005 – date chosen at random) and she only had a similar problem once with an unidentified patient (date not specified). The animal does not leave the house for walks. No further information is available. UPDATE 19 JUN 2018 – The owner contacted and according to her there was an application of FL in December (10 Dec 2017 – date chosen at random) and by that time she also had another dog in her house (the owner did not specify if this dog received FL) and believe that this dog was responsible for the others to have fleas. According to the owner 20 days after the application (30 Dec 2017 – date chosen at random) her animal presented fleas again. The owner treated the environment and on 5 May 2018 she applied FL again but without results. The dog sleeps in blankets and the owner applied Pulgoff on these blankets. Last week the owner used FRONTLINE PLUS ® and the animal recovered from flea infestation. The animal does not leave the house. No further information is available. |
| 14-Jun-2018 | UAE; 18BR004216; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 14.00 Month(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 30-May-2018 | 31-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Elvis Presley, a 14-month-old, 5 kg, male, Shih Tzu, was treated with one vial of FRONTLINE PLUS DOG S (FL) (023/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 15 days ago (30 May 2018) and another vial of FL one week ago (7 Jun 2018), for flea treatment. Lack of efficacy suspected because the dog continued to have fleas. Flea infestation one week prior to FL, environment not treated. No further information is available. |
| 13-Jun-2018 | UAE; 18BR004217; RJ; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / | 01-Jan-2018* | 13-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Bolinha, a 2-month-old, 1.1 kg, male, Yorkshire Terrier, was treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, back and paws, by the reporter, on 12 Jun 2018 afternoon, for tick treatment. Starting on 13 Jun 2018 morning, the pup experienced apathy, diarrhea, vomiting and seizure. Bolinha was taken to the vet and remains hospitalized (details not provided). FRONTLINE was |

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| | | Month(s)<br>**Weight:** 1.1 kg | | | | Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | applied in the past by another person with no issues (date not specified – 1 May 2018 chosen at random). This is the extent of the information available. |
| 14-Jun-2018 | UAE; 18BR004226; SP; Brazil | **Species:** Canine<br>**Breed:** Canine Other<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 11.00 Year(s)<br>**Weight:** 40 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 14-Jun-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Aquiles, 11 years old, 40 kilograms, canine, female, Berger Blanc Suisse, received 1 pipette of FRONTLINE PLUS DOG L (FL) (lot 024/17 and exp date unknown, topically, between the shoulder blades), applied by the owner on 6 Jun 2018, for flea treatment. The owner complained that she continues to see fleas in her pet. According to the owner, animal already had fleas 3 days prior to FL application. The environment has not been treated with a specific product. It is unknown if the animal already received FL in the past. No further information is available. |
| 14-Jun-2018 | UAE; 18BR004227; MG; Brazil | **Species:** Feline<br>**Breed:** Persian (No Further Description)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 14-Jun-2018 | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Brad Pitt, a male Persian of 2 years old and 6 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (001/17, Dec 2018, topical, btw the shoulder blades), applied by the reporter on 13 Jun 2018, for flea control. Lack of efficacy is suspected because one flea was found on her pet today (14 Jun 2018). The environment has not been treated and it is unknown if FL has previously been applied. There is another cat in this household that was not treated with FL. No further information is expected. UPDATE 19 JUN 2018 – The cat is still infested by fleas. The environment was not treated yet. There is no further information expected. |
| 13-Jun-2018 | UAE; 18BR004234; -; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 20.00 Month(s)<br>**Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 13-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, an unidentified, female, small breed, dog received for the first time 1 pipette of FRONTLINE (FL) (lot 001/17 and exp date DEC 2018, route and site of administration unknown), applied by an unknown person on an unknown date (12 Jun 2018 – date chosen at random), for flea treatment. The owner complained that her dog continues with fleas after FL application. According to her, she adopted a young kitten and she came with fleas. The environmental conditions are unknown. The owner was used to apply a different product. No further information is available. UPDATE 15 JUN 2018 – Nina, a 20-month-old, 10 kg, female, crossbred dog, was treated with FRONTLINE SPRAY (FL) (001/17, Dec 2018), topic, not on whole body, by the reporter, one week ago (8 Jun 2018). Flea infestation 2 days prior to FL, environment not treated. One cat of the same household that is also on FL was reported on 18BR004249. There is no further information expected. |
| 15-Jun-2018 | UAE; 18BR004236; SP; Brazil | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products** | 01-Apr-2018* | 15-Jun-2018* | 6 Week(s) 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Luck, a male Shih Tzu of 90 days old and 4.2 kg, was treated with FRONTLINE SPRAY (FL) (002/17, Dec 2018, topical, btw the shoulder blades to the tail), applied by the reporter on 1 Apr 2018 |

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| | | Unknown<br>**Age:** 90.00 Day(s)<br>**Weight:** 4.2 kg | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | (estimated date) and 1 May 2018 (estimated date), for flea control. Lack of efficacy is suspected because the pet is infested by fleas . The environment has been treated with deltamethrin. No further information is expected. |
| 14-Jun-2018 | UAE; 18BR004237; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 18.00 Month(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 13-Jun-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nick, an 18-month-old, male, Yorkshire Terrier (weight unknown), was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, between the shoulder blades and near the tail, by the reporter, on 1 Jun 2018, for flea and tick prevention. Lack of efficacy suspected because the veterinarian discovered fleas and ticks on Nick yesterday (13 Jun 2018). Environment treated with Butox, outdoor access. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 15-Jun-2018 | UAE; 18BR004238; RJ; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2018* | 15-Jun-2018* | 29 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female mixed breed cat of 7 years old and 2 kg, was treated with FRONTLINE SPRAY (FL) (001/17, exp date unknown, topical, whole body), applied by the reporter on 17 May 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Flea infestation 2 months prior to FL. The environment has not been treated. FL was applied in the past with no issue (1 Jan 2018 - chosen at random). No further information is expected. |
| 15-Jun-2018 | UAE; 18BR004241; SP; Brazil | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Year(s)<br>**Weight:** 28 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 15-Jun-2017* | 15-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Boni, 9 years old, 28 kilogram, canine, male, Mixed Breed, received a dose of FRONTLINE SPRAY (FL) (lot 002/17 and exp date unknown, topically in the whole body), applied by the owner for the last time 1 week ago (8 Jun 2018 – estimated date), for flea treatment. The owner complained that her dog continues with fleas after FL application. According to her, the animal already had fleas 2 months prior to FL. The owner said that she applied FL for several times (1 Jun 2018 – date chosen at random). There are another 2 dogs in the same household with similar problem (see cases 18BR004242 and 18BR004243). The owner also complained about an adverse event (see case 18BR004244). The environment has not been treated. No further information is available. UPDATE 18 JUN 2018 – The owner was contacted and said that her animal continues with fleas and she does not see fleas in the environment. According to the owner, it was not the first time she has used FL (15 Jun 2017 – date chosen at random) |

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| | | | | | | | | | | | and the last application of FL has been around 1 month ago (8 Jun 2018 – estimated date). No further information is available. |
| 15-Jun-2018 | UAE; 18BR004242; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 15-Jun-2017* | 15-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sofia, 3 years old, 6 kilogram, canine, female, Shih Tzu, received a dose of FRONTLINE SPRAY (FL) (lot 002/17 and exp date unknown, topically in the whole body), applied by the owner for the last time 1 week ago (8 Jun 2018 – estimated date), for flea treatment. The owner complained that her dog continues with fleas after FL application. According to her, the animal already had fleas 2 months prior to FL. The owner said that she applied FL for several times (1 Jun 2018 – date chosen at random). There are another 2 dogs in the same household with similar problem (see cases 18BR004241 and 18BR004243). The owner also complained about an adverse event (see case 18BR004244). The environment has not been treated. No further information is available. UPDATE 18 JUN 2018 – The owner was contacted and said that her animal continues with fleas and she does not see fleas in the environment. According to the owner, it was not the first time she has used FL (15 Jun 2017 – date chosen at random) and the last application of FL has been around 1 month ago (8 Jun 2018 – estimated date). No further information is available. |
| 15-Jun-2018 | UAE; 18BR004243; SP; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 15-Jun-2017* | 15-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Catarina, 9 months old, 3 kilogram, canine, female, Shih Tzu, received a dose of FRONTLINE SPRAY (FL) (lot 002/17 and exp date unknown, topically in the whole body), applied by the owner for the last time 1 week ago (8 Jun 2018 – estimated date), for flea treatment. The owner complained that her dog continues with fleas after FL application. According to her, the animal already had fleas 2 months prior to FL. The owner said that she applied FL for several times (1 Jun 2018 – date chosen at random). There are another 2 dogs in the same household with similar problem (see cases 18BR004241 and 18BR004242). The owner also complained about an adverse event (see case 18BR004244). The environment has not been treated. No further information is available. UPDATE 18 JUN 2018 – The owner was contacted and said that her animal continues with fleas and she does not see fleas in the environment. According to the owner, it was not the first time she has used FL (15 Jun 2017 – date chosen at random) and the last application of FL has been around 1 month ago (8 Jun 2018 – estimated date). No further information is available. |
| 15-Jun-2018 | UAE; 18BR004244; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 15-Jun-2017* | 05-Jun-2018* | N/A | D-C | Suspected Adverse Event: As reported by the pet owner, Sofia, 3 years old, 6 kilogram, canine, female, Shih Tzu, received a dose of FRONTLINE SPRAY (FL) (lot 002/17 and exp date unknown, topically in the whole body), applied by the owner for the last time 1 week ago (8 Jun 2018 – estimated date), for flea treatment. According to the owner, an application of FL was performed by a DVM in an unspecified date and after that, the animal presented vomiting and panting (5 Jun 2018 - date chosen at random). The animal recovered hours after. No further information is available. UPDATE 18 JUN 2018 – The owner was contacted and said it was not the first time she has used FL (15 Jun 2017 – date chosen at random). The owner said that she took her animals to a travel and Sofia returned with fleas. According to the owner, she did not saw fleas falling from her pet after FL application as she was used to . The owner then took the animal to a DVM to apply FL again. FL was applied by the DVM and the animal started to 'vomiting" a |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | white foam (hypersalivation) and around 15 to 20 minutes later, the animal recovered by its own. The owner said that the last application of FL has been around 1 month ago (8 Jun 2018 – estimated date). No further information is available. |
| 15-Jun-2018 | UAE; 18BR004247; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 15-Jun-2018* | 26 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Fuchi, 8 months old, 3 kilograms, feline, male, Mixed Breed, received a dose of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topically, between the shoulder blades), applied by the owner on 20 May 2018, for flea treatment. The owner complained that her cat continues with fleas and some 'black spots' after FL application. The environment has not been treated. It is unknown if the animal already had FL in the past. No further information is available. |
| 13-Jun-2018 | UAE; 18BR004249; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 0.9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 13-Jun-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mya, a 3-month-old, 0.9 kg, female, mixed breeds cat, was treated with FRONTLINE SPRAY (FL) (001/17, exp unknown), topic, not on whole body, by the reporter, one week ago (8 Jun 2018), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas. Flea infestation 2 days prior to FL, environment not treated. 1 dog of the same household that is also on FL was reported on 18BR004234. No further information is available. |
| 15-Jun-2018 | UAE; 18BR004255; -; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 10-Dec-2015* | 14-Jun-2018 | 30 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner by e-mail, an unidentified cat, female, received a dose of FRONTLINE SPOT-ON CAT (FL) (lot, exp date, route and site of administration are unknown), applied by the owner 30 days ago (15 May 2018 – estimated date), for flea treatment. The owner complained that FL initially work but fleas had returned to her animal. The environmental conditions are unknown. It is unknown if the animal already received FL in the past. No further information is available. UPDATE 19 JUN 2018 – Nina is a 9 years old, 9 kilogram, feline, female, Mixed Breed, received 1 pipette of FL (topically, between the shoulder blades). The husband´s owner told that they travel with Nina to a beach and when they returned, they noticed her scratching. After 3 days, FL was applied and on 14 Jun 2018 his wife found fleas on Nina. The environment has not been treated. The owner already applied FL in his pet before (10 Dec 2015 – date chosen at random). No further information is available. |
| 18-Jun-2018 | UAE; 18BR004256; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Month(s) | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / | 03-Jun-2018* | 18-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Kaco, 10 months old, 4.5 kilogram, canine, male, Shih Tzu, received FRONTLINE SPRAY (FL) (lot 017/16, exp date, topically, in the whole body), applied by the owner for the first time 15 days ago (3 Jun 2018 – estimated date) and the second time 1 week ago (11 Jun 2018 – estimated date), for tick control. The owner complained that FL did not work and she found ticks in her animal. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 4.5 kg | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | The environment has not been treated and the animal does daily walks on the street. There is also another dog in the same household with a similar problem (see cases 18BR004257). No further information is available. |
| 18-Jun-2018 | UAE; 18BR004257; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 03-Jun-2018* | 18-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mia, 7 years old, 3 kilogram, canine, female, Yorkshire, received FRONTLINE SPRAY (FL) (lot 017/16, exp date, topically, in the whole body), applied by the owner for the first time 15 days ago (3 Jun 2018 – estimated date) and the second time 1 week ago ( 11 Jun 2018 – estimated date), for tick control. The owner complained that FL did not work and she found ticks in her animal . The environment has not been treated and the animal does daily walks on the street. There is also another dog in the same household with a similar problem (see cases 18BR004256). No further information is available. |
| 15-Jun-2018 | UAE; 18BR004263; SP; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Year(s)<br>**Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 10-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Pingo, a 12-year-old, 15 kg, male, crossbred dog, was treated with FRONTLINE SPRAY (FL) (003/17, exp unknown), topic, back and belly, by the reporter, several times since last month (date not specified – 10 Jun 2018 chosen at random for last application), for flea treatment. The owner believes that FL is not working as well as it used to because the dog continued to have fleas. Flea infestation prior to FL, environment treated with Arraze every week . FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2017 chosen at random). 2 other dogs of the same household that are also on FL were reported on 18BR004264 and 18BR004265. No further information is available. |
| 15-Jun-2018 | UAE; 18BR004264; SP; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 10.00 Year(s)<br>**Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 10-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a 10-year-old, 10 kg, female, crossbred dog, was treated with FRONTLINE SPRAY (FL) (003/17, exp unknown), topic, back and belly, by the reporter, several times since last month (date not specified – 10 Jun 2018 chosen at random for last application), for flea treatment. The owner believes that FL is not working as well as it used to because the dog continued to have fleas. Flea infestation prior to FL, environment treated with Arraze every week . FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan 2017 chosen at random). 2 other dogs of the same household that are also on FL were reported on 18BR004263 and 18BR004265. No further information is available. |
| 15-Jun-2018 | UAE; 18BR004265; SP; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 19.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 01-Jan-2017* | 10-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sandy, a 19-year-old, 3 kg, female, crossbred dog, was treated with FRONTLINE SPRAY (FL) (003/17, exp unknown), topic, back and belly, by the reporter, several times since last month (date not specified – 10 Jun 2018 chosen at random for last application), for flea treatment. The owner believes that FL is not working as well as it used to because the dog continued to have fleas. Flea infestation prior to FL, environment treated with Arraze every week . FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified – 1 Jan |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** No (Treatment / vaccination program not respected) | | | | | 2017 chosen at random). 2 other dogs of the same household that are also on FL were reported on 18BR004263 and 18BR004264. No further information is available. |
| 18-Jun-2018 | UAE; 18BR004266; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 15-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by pet owner, Bili, a 5-year-old, 7 kg, male, Shih Tzu, was treated with one vial of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 14 Jun 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation 3 days prior to FL, environment treated with Butox, outdoor access 3 times daily. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 18-Jun-2018 | UAE; 18BR004267; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 15-Jun-2018* | 23 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Yoda, a 2-year-old, 5 kg, male mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 23 May 2018, for flea treatment. Lack of efficacy suspected because the owner has discovered fleas on her cat since 15 Jun 2018. Flea infestation one month prior to FL, environment treated. It is unknown if FRONTLINE was applied to the cat in the past. One other cat of the same household that is also on FL was reported on 18BR004268. No further information is available. |
| 18-Jun-2018 | UAE; 18BR004268; RJ; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 15-Jun-2018* | 23 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Luck, a 7-month-old, 1 kg, male mixed breeds cat, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 23 May 2018, for flea treatment. Lack of efficacy suspected because the owner has discovered fleas on her cat since 15 Jun 2018. Flea infestation one month prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the cat in the past. One other cat of the same household that is also on FL was reported on 18BR004267. No further information is available. |
| 18-Jun-2018 | UAE; 18BR004280; SP; Brazil | **Species:** Canine **Breed:** Poodle (Toy) **Sex:** F **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 6.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No | N/A | 18-Jun-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Duda, a female Poodle of 9 years old and 6.5 kg, was treated with an unknown dose of FRONTLINE PLUS DOG XL (lot and exp date are unknown, topical, btw the shoulder blades - the product was fractioned), applied by the reporter on 12 Jun 2018, for flea treatment. Flea infestation 1 month prior to FL. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases reported on 18BR004281, 18BR004282, 18BR004283, 18BR004284 and 18BR004285. No further information is expected. |

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| | | | | | | (Treatment / vaccination program not respected) | | | | | |
| 18-Jun-2018 | UAE; 18BR004281; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 18-Jun-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Marley, a male small crossbred dog of 10 years old and 8 kg, was treated with an unknown dose of FRONTLINE PLUS DOG XL (lot and exp date are unknown, topical, btw the shoulder blades - the product was fractioned), applied by the reporter on 12 Jun 2018, for flea treatment. Flea infestation 1 month prior to FL. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases reported on 18BR004280, 18BR004282, 18BR004283, 18BR004284 and 18BR004285. No further information is expected. |
| 18-Jun-2018 | UAE; 18BR004282; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 18-Jun-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lep, a male small crossbred dog of 12 years old and 4 kg, was treated with an unknown dose of FRONTLINE PLUS DOG XL (lot and exp date are unknown, topical, btw the shoulder blades - the product was fractioned), applied by the reporter on 12 Jun 2018, for flea treatment. Flea infestation 1 month prior to FL. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases reported on 18BR004280, 18BR004281, 18BR004283, 18BR004284 and 18BR004285. No further information is expected. |
| 18-Jun-2018 | UAE; 18BR004283; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 18-Jun-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Custelinha, a male small crossbred dog of 5 years old and 9 kg, was treated with an unknown dose of FRONTLINE PLUS DOG XL (lot and exp date are unknown, topical, btw the shoulder blades - the product was fractioned), applied by the reporter on 12 Jun 2018, for flea treatment. Flea infestation 1 month prior to FL. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases reported on 18BR004280, 18BR004281, 18BR004282, 18BR004284 and 18BR004285. No further information is expected. |

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| 18-Jun-2018 | UAE; 18BR004284; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 6.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 18-Jun-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Coragem, a male small crossbred dog of 6 years old and 8 kg, was treated with an unknown dose of FRONTLINE PLUS DOG XL (lot and exp date are unknown, topical, btw the shoulder blades - the product was fractioned), applied by the reporter on 12 Jun 2018, for flea treatment. Flea infestation 1 month prior to FL. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases reported on 18BR004280, 18BR004281, 18BR004282, 18BR004283 and 18BR004285. No further information is expected. |
| 18-Jun-2018 | UAE; 18BR004285; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 18-Jun-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bolt, a male small crossbred dog of 4 years old and 3 kg, was treated with an unknown dose of FRONTLINE PLUS DOG XL (lot and exp date are unknown, topical, btw the shoulder blades - the product was fractioned), applied by the reporter on 12 Jun 2018, for flea treatment. Flea infestation 1 month prior to FL. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. Similar cases reported on 18BR004280, 18BR004281, 18BR004282, 18BR004283 and 18BR004284. No further information is expected. |
| 18-Jun-2018 | UAE; 18BR004286; SC; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Year(s) **Weight:** 7.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 18-Jun-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Marley, a male small crossbred dog of 9 years old and 7.5 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 13 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was also applied on 30 May 2018 but the pet remained with fleas. FRONTLINE was usually applied in the past with no issues (dose frequency unknown and first dose on date not specified - 1 Jan 2017 chosen at random). No further information is expected. |
| 19-Jun-2018 | UAE; 18BR004288; SP; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | 12-Apr-2018* | 19-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Melissa, a female Shih Tzu of 8 years old and 5 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 5 kg | | | | 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | reporter one week ago (12 Jun 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has not been treated. FL has been applied for 2 consecutives months with the same problem (12 Apr 2018 and 12 May 2018 - dates chosen at random). No further information is expected. |
| 19-Jun-2018 | UAE; 18BR004292; MG; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 18.00 Month(s)<br>**Weight:** 3.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 19-Jun-2018* | 18 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner Clara, 18 months old, 3.8 kilograms, Feline, female, neutered, Mixed Breed, received 1 pipette of FRONTLINE SPOT-ON CAT (FL) (lot, exp date, topically, between the shoulder blades ), applied by a DVM on 1 Jun 2018, for flea treatment. The owner complained that she finds fleas everyday in her cat. According to the owner, animal already had fleas 10 days prior to treatment. The environment has not been treated. There is another cat that also received FL but he ran away from home a week ago . The owner only complaint about Clara´s flea infestation. The animal does not leave the house. It is unknown if the animal already had FL in the past. No further information is available. |
| 19-Jun-2018 | UAE; 18BR004297; SP; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 8.00 Year(s)<br>**Weight:** 13 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 10-Oct-2010* | 12-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Beethoven, 8 years old, 13 kilogram, canine, male, Mixed Breed, received a dose of FRONTLINE SPRAY (FL) (lot and exp date unknown, topically in the whole body), applied by the owner last week (12 Jun 2018 – estimated date), for flea treatment. The owner complained that her dog continued with fleas and that the product had no effect. According to her, the animal already had fleas 2 days prior to FL. The environment has been treated with sodium hypochlorite. The dog goes out to daily walks on the street. The owner already used FL in the past because according to her, the product did not work 'this time" (10 Oct 2010 – date chosen at random). No further information is available. |
| 19-Jun-2018 | UAE; 18BR004298; SC; Brazil | **Species:** Canine<br>**Breed:** Poodle (Toy)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 13.00 Year(s)<br>**Weight:** 3.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 18-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Brenda, a female Poodle Toy of 13 years old and 3.2 kg, was treated with one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), administered by the reporter on 18 Jun 2018, for flea/tick control. The pet has history of vomiting after any oral product. The dog was in good health prior to FL. Two hours after product application, the pet presented with itching and application site reddening. Brenda was bathed, but the symptoms are still ongoing. FL has been applied previously with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). No further information is available. |
| 19-Jun-2018 | UAE; 18BR004300; RJ; Brazil | **Species:** Canine<br>**Breed:** Terrier Breeds (500 Series)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 10.00 Year(s)<br>**Weight:** 13 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 01-Jan-2017* | 19-Jun-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Isabel, a female Fox Paulistinha (Brazilian Terrier) of 10 years old and 13 kg, received one vial of FRONTLINE SPOT-ON DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 16 Jun 2018, for flea/tick control. Lack of efficacy is suspected because the pet has fleas . The environment has been treated with deltamethrin. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). No further information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Yes | | | | | |
| 19-Jun-2018 | UAE; 18BR004309; DF; Brazil | **Species:** Canine **Breed:** Schnauzer **Sex:** M **Sex qualifier:** - **Age:** 35.00 Day(s) **Weight:** Unknown | 14 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 15-Jun-2018* | 16-Jun-2018* | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the veterinarian (who is also the pet owner), one 35-day-old, male, Schnauzer dog (weight unknown), was treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, not on whole body, by the reporter, for the first time, on date not specified (15 Jun 2018 chosen at random), for flea and tick treatment. The puppy was in good health prior to FL. One day post product application, the pup experienced vomiting (once) and prostration. He was treated with antitoxic and recovered 40 minutes later. SLOE cases reported on 18BR004310 and 18BR004311. No further information is available. |
| 19-Jun-2018 | UAE; 18BR004310; DF; Brazil | **Species:** Canine **Breed:** Schnauzer **Sex:** M **Sex qualifier:** - **Age:** 35.00 Day(s) **Weight:** Unknown | 5 | 2 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 15-Jun-2018* | 15-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the veterinarian (who is the pet owner also), 5 35-day-old, male, Schnauzer dog (weight unknown), were treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, not on whole body, by the reporter, for the first time, on date not specified (15 Jun 2018 chosen at random), for flea and tick treatment. Lack of efficacy suspected because2 pups continued to have fleas and ticks. Flea and tick infestation one week prior to FL, environment not treated. Similar case reported on 18BR004311. SAE case reported on 18BR004309. No further information is available. |
| 19-Jun-2018 | UAE; 18BR004311; DF; Brazil | **Species:** Canine **Breed:** Schnauzer **Sex:** F **Sex qualifier:** - **Age:** 35.00 Day(s) **Weight:** Unknown | 9 | 2 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 15-Jun-2018* | 15-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the veterinarian (who is the pet owner also), 9 35-day-old, female, Schnauzer dog (weight unknown), were treated with FRONTLINE SPRAY (FL) (lot and exp unknown), topic, not on whole body, by the reporter, for the first time, on date not specified (15 Jun 2018 chosen at random), for flea and tick treatment. Lack of efficacy suspected because some pups continued to have fleas and ticks. Flea and tick infestation one week prior to FL, environment not treated. Similar case reported on 18BR004310. No further information is available. |
| 20-Jun-2018 | UAE; 18BR004312; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Month(s) | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the** | N/A | 20-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mia, an 8-month-old, 2 kg, female mixed breeds cat, was treated with one vial of FRONTLINE SPOT-ON CAT (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, 15 days ago (5 Jun 2018), for flea treatment. The owner believes that FL worked for only 15 days because her cat is infested by fleas again. Flea infestation few weeks prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the cat in the past. No further information is available. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 2 kg | | | | **product used ok?:** Yes | | | | | |
| 20-Jun-2018 | UAE; 18BR004314; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 20-Jun-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bisteka, a female small crossbred dog of 10 years old and 8 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 11 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, the pet is scratching herself due to fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (See case 18BR004315). No further information is expected. |
| 20-Jun-2018 | UAE; 18BR004315; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 20-Jun-2018* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Cacau, a female small crossbred dog of 4 years old and 9 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 11 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, the pet is scratching herself due to fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. There is another dog in this household with the same issue (See case 18BR004314). No further information is expected. |
| 19-Jun-2018 | UAE; 18BR004323; SC; Brazil | **Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** 20 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 11-Apr-2018 | 19-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Deko, a male Cocker Spaniel of 12 years old and 20 kg, was treated with FRONTLINE SPRAY (FL) (022/14, Jun 2019, route and location are unknown), applied by the reporter on 17 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and cypermethin. FL has been applied since 11 Apr 2018 with the same issue. No further information is expected. |
| 21-Jun-2018 | UAE; 18BR004324; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Month(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 21-Jun-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lua, a female Yorkshire of 5 months old and 2 kg, was treated with FRONTLINE SPRAY (FL) (012/16, Aug 2018), topical, whole body, applied by the reporter one month ago (21 May 2018), for tick treatment. Lack of efficacy is suspected because the pet remains with live ticks. The environment has been treated with Triatox® and Butox®. It is unknown if FL has previously been applied. There is another dog in this household with the same issue (see case 18BR004325). No further information is expected. |
| 21-Jun-2018 | UAE; 18BR004325; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products** | N/A | 21-Jun-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Puff, a male Yorkshire of 7 months old and 2.6 kg, was treated with FRONTLINE SPRAY (FL) (012/16, Aug 2018), topical, whole body, applied by the reporter one month ago (21 May 2018), for tick |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 2.6 kg | | | | **used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with Triatox® and Butox®. It is unknown if FL has previously been applied. There is another dog in this household with the same issue (see case 18BR004324). No further information is expected. |
| 21-Jun-2018 | UAE; 18BR004326; BA; Brazil | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 19-Jun-2018 | 20-Jun-2018 | 1 Day(s) | D-C | Suspected Adverse Event: As reported by the pet owner, Bob, a male Shih Tzu of 5 years old and around 8 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown), topical, btw the shoulder blades, applied by the reporter on 19 Jun 2018, for flea/tick treatment. The pet was in good health prior to FL. One day after product application, the pet presented with pasty diarrhea and vomiting. The symptoms are still ongoing. In addition, Bob is not eating and he is apathetic. No vet care was provided until now. An unknown medication for the 'stomach' was administered by the owner, but the pet didn't show any improvement. No further information is available. |
| 21-Jun-2018 | UAE; 18BR004327; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 05-Jun-2018 | 21-Jun-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dom, a male mixed breed cat of 7 months old and 4 kg, was treated with FRONTLINE SPRAY (FL) (003/17, unknown exp date, following 'instructions on the label'), applied by the reporter for the first time on 5 Jun 2018 and for the second time on 16 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. No further information is expected. |
| 21-Jun-2018 | UAE; 18BR004328; SP; Brazil | **Species:** Canine **Breed:** Basset Hound **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 21-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Kate, a female Basset of 14 years old and 10 kg, was treated with FRONTLINE SPRAY (FL) (002/17, Dec 2018, topical, parts of the body), applied by the reporter one week ago (14 Jun 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. The dog has no outdoor access. No further information is expected. |
| 20-Jun-2018 | UAE; 18BR004332; -; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products** | N/A | 20-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Pingo, a male dog of 13 years old (other signalment is unknown), received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter around 15 days ago (5 Jun 2018 - estimated date). Lack of efficacy is suspected because the dog has fleas. This is the extent of the |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** 13.00 Year(s)<br>**Weight:** 18 kg | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | information available. UPDATE 25 JUN 2018 - Pingo, a male medium crossbred dog of 18 kg was treated with FRONTLINE PLUS DOG M (FL), topical, btw the shoulder blades, applied by the reporter on 4 Jun 2018, for flea control. It is unknown if FL has previously been applied. Another product against ectoparasites (Advantage® Max 3) was applied and now the pet is free of fleas. The environment has not been treated. No further information is expected. |
| 22-Jun-2018 | UAE; 18BR004334; SC; Brazil | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 22-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, more than one female cat of unknown signalment were treated with FRONTLINE (unsubstantiated) (lot and exp unknown), by the reporter (route and location unknown), on date not specified (15 Jun 2018 chosen at random), for flea control. Lack of efficacy suspected because the cats were infested by fleas. This is the extent of the information available. |
| 22-Jun-2018 | UAE; 18BR004341; SP; Brazil | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 03-May-2018 | 04-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As initially reported by the pet owner via e-mail, one female cat of unknown signalment was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp unknown), by the reporter, 50 days ago (3 May 2018) and 'last week' (15 Jun 2018 chosen at random), for flea treatment. Lack of efficacy suspected because the cat continued to have fleas . Outdoor access and contact to other pets denied. This is the extent of the information available. UPDATE 26 JUN 2018 - Bela is a 7-year-old, 4 kg, female, Siamese cat. FL was applied for the first time on 3 May 2018, then on 16 Jun 2018, topic, base of skull and btw the shoulder blades. Flea infestation 12 days prior to the first application, environment not treated. There is no further information expected. |
| 22-Jun-2018 | UAE; 18BR004345; SP; Brazil | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Year(s)<br>**Weight:** 25 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 05-May-2018* | 05-May-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Snoop, a 12-year-old, 25 kg, male, crossbred dog, was treated with FRONTLINE SPRAY (FL) (002/17, exp unknown), topic, head, back and paws, by the reporter, 20 days ago (5 Jun 2018), for flea treatment. Although the amount of fleas has decreased, lack of efficacy suspected because the dog continued to have fleas . Flea infestation prior to FL, environment treated with Butox, outdoor access. FL was applied once on date not specified (5 May 2018 chosen at random) with same issue. There is no further information available. |
| 25-Jun-2018 | UAE; 18BR004350; GO; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products** | 01-Jan-2017* | 25-Jun-2018* | 24 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a female small crossbred dog of 6 years old and 5 kg, received one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 1 Jun 2018, for tick control. Lack of efficacy is suspected because ticks were found on Belinha. The environment |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 5 kg | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** - | | | | | has not been treated. FL has been applied monthly with no issue (first application was not provided - 1 Jan 2017 chosen at random). No further information is expected. |
| 25-Jun-2018 | UAE; 18BR004351; DF; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jul-2017* | 25-Jun-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Flor, a female small crossbred dog of 3 years old and 8 kg, received one vial of FRONTLINE PLUS DOG S (FL) (023/17, Jul 2019, topical, btw the shoulder blades), applied by the reporter on 22 Jun 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has not been treated. FL has been applied monthly with no issue since date not specified (1 Jul 2017 - chosen at random). There is another dog in this household with the same problem (see case 18BR004352). No further information is expected. |
| 25-Jun-2018 | UAE; 18BR004352; DF; Brazil | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jul-2017* | 25-Jun-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Amora, a female small crossbred dog of 1 year old and 5 kg, received one vial of FRONTLINE PLUS DOG S (FL) (023/17, Jul 2019, topical, btw the shoulder blades), applied by the reporter on 22 Jun 2018, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has not been treated. FL has been applied monthly with no issue since date not specified (1 Jul 2017 - chosen at random). There is another dog in this household with the same problem (see case 18BR004351). No further information is expected. |
| 25-Jun-2018 | UAE; 18BR004354; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 25-Jun-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nino, a male mixed breed cat of 5 years old and 4 kg, received one vial of FRONTLINE SPOT-ON CATS (FL) (005/17, Nov 2018, topical, btw the shoulder blades), applied by the reporter on 20 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR004355, 18BR004356 and 18BR004357. No further information is expected. |
| 25-Jun-2018 | UAE; 18BR004355; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.50 Year(s)<br>**Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 25-Jun-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dudu, a male mixed breed cat of 2.5 years old and 2.5 kg, received one vial of FRONTLINE SPOT-ON CATS (FL) (005/17, Nov 2018, topical, btw the shoulder blades), applied by the reporter on 20 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and FL has been applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR004354, 18BR004356 and 18BR004357. No further information is expected. |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 25-Jun-2018 | UAE; 18BR004356; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 25-Jun-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lince, a male mixed breed cat of 2 years old and 5 kg, received one vial of FRONTLINE SPOT-ON CATS (FL) (005/17, Nov 2018, topical, btw the shoulder blades), applied by the reporter on 20 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and FL has been applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR004354, 18BR004355 and 18BR004357. No further information is expected. |
| 25-Jun-2018 | UAE; 18BR004357; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 25-Jun-2018* | 5 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mini, a female mixed breed cat of 15 years old and 2.5 kg, received one vial of FRONTLINE SPOT-ON CATS (FL) (005/17, Nov 2018, topical, btw the shoulder blades), applied by the reporter on 20 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with an unknown product and FL has been applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). Similar cases were reported on 18BR004354, 18BR004355 and 18BR004356. No further information is expected. |
| 23-Jun-2018 | UAE; 18BR004358; PB; Brazil | **Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 10-Oct-2015* | 23-Jun-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Bianca, 7 years old, 35 kilograms, canine, female, Pit Bull, received 1 pipette of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner on 15 Jun 2018, for flea treatment. The owner complained that it has been 2 weeks since she applied FL but she continues to see fleas in her pet. The environment has been treated with Nitronox. There is also another dog in the same household with a similar problem (see case 18BR004359) and also another cat (see case 18BR004360). The owner already used FL in the past (10 Oct 2015 – date chosen at random). No further information is available. |
| 23-Jun-2018 | UAE; 18BR004359; PB; Brazil | **Species:** Canine **Breed:** Large crossbred (>20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 30 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 10-Oct-2015* | 23-Jun-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Meninão, 10 years old, 30 kilograms, canine, male, Mixed Breeds, received 1 pipette of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner on 15 Jun 2018, for flea treatment. The owner complained that it has been 2 weeks since she applied FL but she continues to see fleas in her pet. The environment has been treated with Nitronox. There is also another dog in the same household with a similar problem (see case 18BR004358) and also another cat (see case 18BR004360). The owner already used FL in the past (10 Oct 2015 – date chosen at random). No further information is available. |
| 23-Jun-2018 | UAE; 18BR004360; PB; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous | 01-Jan-2017* | 23-Jun-2018* | 8 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Juarez, 3 years old, 7 kilograms, feline, male, Mixed Breeds, received 1 pipette of FRONTLINE SPOT-ON CAT (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner on 15 Jun 2018, for flea treatment. The owner complained that it has been 2 weeks since she applied FL but she continues to see fleas in her pet. The environment has been treated with Nitronox. There are also 2 dogs in the same |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 7 kg | | | | **Was the product used ok?:** Yes | | | | | household with a similar problem (see case 18BR004358 and 18BR004359). The owner already used FL in the past (1 Jan 2017 – date chosen at random). No further information is available. |
| 25-Jun-2018 | UAE; 18BR004366; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 10-Oct-2015* | 06-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, 4 years old, 4 kilograms, canine, female, Poodle, received 1 pipette of FRONTLINE SPOT-ON DOG (FL)(unsubstantiated) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner on 5 Jun 2018, for tick treatment. The owner also applied FRONTLINE PLUS DOGS S (FP) (lot and exp date unknown, topically , between the shoulder blades) on 17 Jun 2018. The owner complained that FL did not treat ticks and then she applied FP which did not work too and she continued to see ticks on her pet. According to the owner, animal already had ticks 2 days prior to treatment. The environment has not been treated. The dog does not go out for walks on the street. The owner already used FL in the past (10 Dec 2015 – date chosen at random) with no issues. No further information is available. |
| 25-Jun-2018 | UAE; 18BR004367; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 2.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 25-Jun-2018* | 3 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Kyara, 4 months old, 2.1 kilograms, feline, female, Mixed Breed, received 1 pipette of FRONTLINE SPOT-ON CAT (FL) (lot and exp date unknown, topically, between the shoulder blades ), applied by the owner on 22 Jun 2018, for flea treatment. The owner complained that she continues to see fleas in her cat. According to the owner, animal already had fleas 10 days prior to treatment. The environment has not been treated. It is unknown if FL has been used in the past. No further information is available. |
| 25-Jun-2018 | UAE; 18BR004368; SP; Brazil | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2017* | 25-Jun-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Melissa, a female Poodle of 5 years old and 7 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, neck and lumbar), applied by the reporter on 19 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). No further information is expected. |
| 25-Jun-2018 | UAE; 18BR004371; -; Brazil | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown | N/A | 25-Jun-2018* | 6 Week(s) 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, one cat of unknown signalment received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter 45 days ago (10 May 2018 - estimated date), for flea treatment. The owner believes that FL is not working because she found fleas on her pet 45 days after product application. This is the extent of the information available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | to Company | | | | | |
| 26-Jun-2018 | UAE; 18BR004373; SP; Brazil | **Species:** Canine **Breed:** Lhasa Apso **Sex:** F **Sex qualifier:** Unknown **Age:** 18.00 Month(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 13-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by pet owner, Nina, an 18-month-old, 4 kg, female, Lhasa Apso, was treated with one vial of FRONTLINE PLUS DOG S (FL) (018/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 12 Jun 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation 2 months prior to FL, environment treated with Butox, outdoor access denied. It is unknown if FRONTLINE was applied to the dog in the past. Another dog of the same household that is also on FL was reported on 18BR004374. No further information is available. |
| 26-Jun-2018 | UAE; 18BR004374; SP; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 13-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by pet owner, Mel, a 2-year-old, 8 kg, female, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG S (FL) (018/17, exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 12 Jun 2018, for tick treatment. Lack of efficacy suspected because the dog continued to have ticks. Tick infestation 2 months prior to FL, environment treated with Butox, outdoor access. It is unknown if FRONTLINE was applied to the dog in the past. Another dog of the same household that is also on FL was reported on 18BR004373. No further information is available. |
| 25-Jun-2018 | UAE; 18BR004375; SP; Brazil | **Species:** Feline **Breed:** Siamese **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 10-Jun-2018* | 25-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nenê, 2 years old, 2 kilograms, feline, male, Siamese, received a dose of FRONTLINE SPRAY (FL) (lot 017/16 and exp date unknown, topically, unknown site of administration ), applied by the owner for the first time 15 days ago (10 Jun 2018 – estimated date), for flea treatment. The owner complained that she continues to see fleas in her cat. According to the owner, animal already had fleas 2 days prior to treatment. The environment has not been treated. There is also another cat and one dog in the same household with similar problem (see cases 18BR004376 and 18BR004377). No further information is available. |
| 25-Jun-2018 | UAE; 18BR004376; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Month(s) **Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 10-Jun-2018* | 25-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Paçoca, 10 months old, 2 kilograms, feline, male, Mixed Breed, received a dose of FRONTLINE SPRAY (FL) (lot 017/16 and exp date unknown, topically, unknown site of administration ), applied by the owner for the first time 15 days ago (10 Jun 2018 – estimated date), for flea treatment. The owner complained that she continues to see fleas in her cat. According to the owner, animal already had fleas 2 days prior to treatment. The environment has not been treated. There is also another cat and one dog in the same household with similar problem (see cases 18BR004375 and 18BR004377). No further information is available. |
| 25-Jun-2018 | UAE; 18BR004377; SP; Brazil | **Species:** Canine **Breed:** Yorkshire Terrier | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY | 10-Jun-2018* | 25-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Nala, 9 years old, 3 kilograms, canine, male, Yorkshire, received a dose of FRONTLINE SPRAY (FL) (lot 017/16 and exp date |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Year(s)<br>**Weight:** 3 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | unknown, topically, unknown site of administration ), applied by the owner for the first time 15 days ago (10 Jun 2018 – estimated date), for flea treatment. The owner complained that she continues to see fleas in her dog. According to the owner, animal already had fleas 2 days prior to treatment. The environment has not been treated. There is also another 2 cats in the same household with similar problem (see cases 18BR004375 and 18BR004376). No further information is available. |
| 26-Jun-2018 | UAE; 18BR004378; SP; Brazil | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 25 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 26-Jun-2018* | 31 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Ralf, a male large crossbred dog of 4 years old and 25 kg, was treated with FRONLINE SPRAY (FL) (004/17, Jan 2019, topical, whole body), applied by the reporter one month ago (26 May 2018), for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with an unknown product and it is unknown if FL has previously been applied. No further information is expected. |
| 26-Jun-2018 | UAE; 18BR004379; SP; Brazil | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 18.00 Month(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 25-Jun-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mano, 18 months old, 6 kilograms, canine, male, Lhasa Apso, received a pipette of FRONTLINE PLUS DOG S (FL) (lot 018/17 and exp date unknown, topically, between the shoulder blades ), applied by the owner on 11 Jun 2018, for flea and tick control. The owner complained that after 2 weeks (25 Jun 2018 - estimated date), his dog got fleas and ticks. The environment has not been treated. The dog does daily walks on the street. It is unknown if the animal already received FL in the past. No further information is available. |
| 25-Jun-2018 | UAE; 18BR004380; SP; Brazil | **Species:** Canine<br>**Breed:** Fila Brasiliera<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Month(s)<br>**Weight:** 14.1 kg | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Jun-2018 | 21-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Joca, a 3-month-old, 14.1 kg, male, Fila Brasileiro, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, for the first time, on 20 Jun 2018, for flea treatment. Lack of efficacy suspected because the pup continued infested by a large amount of fleas. Joca was infested by fleas and arrived to the household one day prior to FL, environment treated. There are 2 other dogs in the same household that received NEXGARD for tick treatment and they were not infested anymore. No further information is available. |
| 25-Jun-2018 | UAE; 18BR004381; SP; Brazil | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 10.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | 01-Jan-2017* | 25-Jun-2018* | 10 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Kelly, a female Yorkshire of 10 years old and 5 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 15 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). No further information is |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | expected. |
| 26-Jun-2018 | UAE; 18BR004382; RJ; Brazil | **Species:** Canine<br>**Breed:** Canine Other<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Month(s)<br>**Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 26-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Carki, 4 months old, 8 kilograms, canine, male, Berger Blanc Suisse, received a dose of FRONTLINE SPRAY (FL) (lot and exp date unknown, topically, in the whole body ), applied by the owner 1 week ago (19 Jun 2018 – estimated date), for tick treatment. The owner complained that a few days later, she noticed 'spots' sucking the animal´s blood and in the 'spot' site there was blood. According to the owner, animal had parasites 1 day prior to FL application. The environment has been treated with Butox. The owner believes the parasites came from the Veterinarian where Carki took his vaccines. It is unknown if the animal already received FL in the past. No further information is available. |
| 26-Jun-2018 | UAE; 18BR004387; -; Brazil | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2016* | 26-Jun-2018* | 11 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment, was treated with one vial of FRONTLINE PLUS (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 15 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2016 chosen at random). No further information is expected. |
| 26-Jun-2018 | UAE; 18BR004388; RS; Brazil | **Species:** Canine<br>**Breed:** Pug<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Month(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 26-Jun-2018* | 25 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sofia, a female Pug of 6 months old and 5 kg, received, for the first time, one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 14 Jun 2018, for flea control. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with amitraz and it is unknown if FL has previously been applied. No further information is expected. |
| 28-Jun-2018 | UAE; 18BR004397; SP; Brazil | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 15.00 Year(s)<br>**Weight:** 18 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 24-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Totó, 15 years old, 18 kilograms, canine, male, Mixed Breed, received a dose of FRONTLINE PLUS DOG M (FL) (lot 019/17 and exp date unknown, topically, between the shoulder blades ), applied by the owner on 24 Jun 2018, for tick treatment. The owner complained that since he applied FL he keeps removing ticks of his animal. According to the owner, animal had parasites 1 day prior to FL application. The environment has been treated with Butox. The owner believes the parasites comes from his neighbor who also has a dog. The owner said that Totó goes for walks on the street and return without ticks, but by the night, they appear on him. It is unknown if the animal already received FL in the past. No further information is available. |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 28-Jun-2018 | UAE; 18BR004400; RJ; Brazil | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 3.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 21-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Max, a 3-month-old, 3.2 kg, male, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp unknown), topic, base of skull and btw the shoulder blades, by the reporter, on 20 Jun 2018, for flea treatment. Lack of efficacy suspected because the pup continued to have fleas. Flea infestation one month prior to FL, environment not treated. It is unknown if FRONTLINE was applied to the dog in the past. No further information is available. |
| 28-Jun-2018 | UAE; 18BR004410; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** 13.00 Month(s) **Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 26-Jun-2018 | 28-Jun-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Joca, a male mixed breed cat of 13 months old and 1.5 kg, received, for the first time, one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 26 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . The environment has not been treated. No further information is expected. |
| 26-Jun-2018 | UAE; 18BR004413; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 13 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 26-Jun-2018* | 16 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one dog of unknown signalment was treated with one vial of FRONTLINE PLUS DOGS (FL) (size, lot and exp unknown), by the reporter, on 10 Jun 2018, for flea treatment. Lack of efficacy suspected because 2 fleas were discovered on her dog today (26 Jun 2018). The owner had already issues in the past post FRONTLINE SPOT-ON DOGS application (SLOE cases 18BR000779 and 18BR000823). This is the extent of the information available. UPDATE 29 JUN 2018 – Thor, a 5-year-old, 13 kg, male, crossbred dog, was treated with one vial of FRONTLINE PLUS DOG M (FL), topic, base of skull and btw the shoulder blades. Environment treated. FRONTLINE has not been applied since Dec 2017. There is another dog in the same household that is on other company's product and is not infested by fleas. No further information is available. |
| 29-Jun-2018 | UAE; 18BR004414; RJ; Brazil | **Species:** Feline **Breed:** Maine Coon Cat **Sex:** F **Sex qualifier:** Unknown **Age:** 4.00 Month(s) **Weight:** 2.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 22-Jun-2018 | 23-Jun-2018* | N/A | D-E | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dolores, 4 months old, 2.5 kilograms, feline, female, Maine Coon, received an unknown dose of FRONTLINE SPRAY (FL) (lot 002/17 and exp date DEC 2019, topically, in the whole body), applied by the owner twice, the first time 1 week ago (22 Jun 2018) and the second one 4 days later (26 Jun 2018), for flea treatment. The owner complained that he continues to see fleas in his cat. According to the owner, the animal already had fleas 1 day prior to treatment. The environment has not been treated. There is also another cat in the same household with similar problem (see case 18BR004415). No further information is available. |
| 29-Jun-2018 | UAE; 18BR004415; | **Species:** Feline **Breed:** Maine | 1 | 1 | 0 | **Product used:** FIPRONIL | 22-Jun-2018 | 23-Jun-2018* | N/A | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Percival, 6 months old, 3.1 kilograms, feline, male, Maine Coon, |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | RJ; Brazil | Coon Cat<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Month(s)<br>**Weight:** 3.1 kg | | | | SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | received an unknown dose of FRONTLINE SPRAY (FL) (lot 002/17 and exp date DEC 2019, topically, in the whole body), applied by the owner twice, the first time 1 week ago (22 Jun 2018) and the second one 4 days later (26 Jun 2018), for flea treatment. The owner complained that he continues to see fleas in his cat. According to the owner, the animal already had fleas 1 day prior to treatment. The environment has not been treated. There is also another cat in the same household with similar problem (see case 18BR004414). No further information is available. |
| 29-Jun-2018 | UAE; 18BR004417; RS; Brazil | **Species:** Canine<br>**Breed:** Siberian Husky<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 18.00 Month(s)<br>**Weight:** 25 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 26-Jun-2018 | 28-Jun-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Aurora, a female Siberian Husky of 18 months old and 25 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG L (FL) (003/16 and unknown exp date, topical, btw the shoulder blades), applied by the reporter on 26 Jun 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, the pet is scratching herself due to fleas. Ticks were found dead. The environment has been treated with amitraz. Similar cases reported on 18BR004418, 18BR004419 and 18BR004420. In addition, 8 puppies were treated with FL SPRAY and they have no issue. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004418; RS; Brazil | **Species:** Canine<br>**Breed:** Siberian Husky<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 20.00 Month(s)<br>**Weight:** 19 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 26-Jun-2018 | 28-Jun-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Delta, a female Siberian Husky of 20 months old and 19 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG L (FL) (003/16 and unknown exp date, topical, btw the shoulder blades), applied by the reporter on 26 Jun 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, the pet is scratching herself due to fleas. Ticks were found dead. The environment has been treated with amitraz. Similar cases reported on 18BR004417, 18BR004419 and 18BR004420. In addition, 8 puppies were treated with FL SPRAY and they have no issue. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004419; RS; Brazil | **Species:** Canine<br>**Breed:** Siberian Husky<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 15 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 26-Jun-2018 | 28-Jun-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Ozzy, a male Siberian Husky of 6 years old and 15 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG L (FL) (003/16 and unknown exp date, topical, btw the shoulder blades), applied by the reporter on 26 Jun 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with fleas . In addition, the pet is scratching himself due to fleas. Ticks were found dead. The environment has been treated with amitraz. Similar cases reported on 18BR004417, 18BR004418 and 18BR004420. In addition, 8 puppies were treated with FL SPRAY and they have no issue. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004420; RS; Brazil | **Species:** Canine<br>**Breed:** Siberian Husky<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other | 26-Jun-2018 | 28-Jun-2018* | 2 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Dantes, a male Siberian Husky of 1 year old and 15 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG L (FL) (003/16 and unknown exp date, topical, btw the shoulder blades), applied by the reporter on 26 Jun 2018, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, the pet is scratching himself due to fleas. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Weight:** 15 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | Ticks were found dead. The environment has been treated with amitraz. Similar cases reported on 18BR004417, 18BR004418 and 18BR004419. In addition, 8 puppies were treated with FL SPRAY and they have no issue. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004428; SP; Brazil | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 13.00 Year(s)<br>**Weight:** 12 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 29-Jun-2018* | 15 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Duda, a female Poodle of 13 years old and 12 kg, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter 15 days ago (14 Jun 2018), for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. The environment has been treated with deltamethrin and it is unknown if FL has previously been applied. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004431; RS; Brazil | **Species:** Canine<br>**Breed:** Maltese<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017* | 29-Jun-2018* | 12 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Princesa, a female Maltese x Poodle of 4 years old and 4 kg, was treated with FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 17 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment conditions are unknown. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided - 1 Jan 2017 chosen at random). No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004439; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Month(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 22-Jun-2018 | 29-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Ganessa, a female mixed breed cat of 2 months old and unknown weight, was treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, not in whole body - off label), applied by the reporter 1 week ago (22 Jun 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. Similar cases reported on 18BR004440, 18BR004441, 18BR004442, 18BR004443 and 18BR004444. The owner also reported an adverse reaction in one cat (18BR004445). PQC reported on 18BR004446. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004440; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous | 22-Jun-2018 | 29-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Akiles, a male mixed breed cat of 2 years old and 5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, not in the whole body), applied by the reporter 1 week ago (22 Jun 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. Similar cases reported on 18BR004439, 18BR004441, 18BR004442, |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 5 kg | | | | **Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | 18BR004443 and 18BR004444. The owner also reported an adverse reaction in one cat (18BR004445). PQC reported on 18BR004446. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004441; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 22-Jun-2018 | 29-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lucky, a female mixed breed cat of 5 years old and 8 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, parts of the body), applied by the reporter 1 week ago (22 Jun 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. Similar cases reported on 18BR004439, 18BR004440, 18BR004442, 18BR004443 and 18BR004444. The owner also reported an adverse reaction in one cat (18BR004445). PQC reported on 18BR004446. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004442; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 22-Jun-2018 | 29-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Sol, a female mixed breed cat of 5 years old and 5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, parts of the body), applied by the reporter 1 week ago (22 Jun 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. Similar cases reported on 18BR004439, 18BR004440, 18BR004441, 18BR004443 and 18BR004444. The owner also reported an adverse reaction in one cat (18BR004445). PQC reported on 18BR004446. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004443; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 22-Jun-2018 | 29-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Triniti, a female mixed breed cat of 14 years old and 5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, parts of the body), applied by the reporter 1 week ago (22 Jun 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. Similar cases reported on 18BR004439, 18BR004440, 18BR004441, 18BR004442 and 18BR004444. The owner also reported an adverse reaction in one cat (18BR004445). PQC reported on 18BR004446. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004444; SP; Brazil | **Species:** Feline **Breed:** Feline mixed/various | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY | 22-Jun-2018 | 29-Jun-2018* | 1 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Isis, a female mixed breed cat of 2 years old and 5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 5 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | are unknown, topical, parts of the body), applied by the reporter 1 week ago (22 Jun 2018), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with deltamethrin. Similar cases reported on 18BR004439, 18BR004440, 18BR004441, 18BR004442 and 18BR004443. The owner also reported an adverse reaction in one cat (18BR004445). PQC reported on 18BR004446. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004445; SP; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 22-Jun-2018 | 23-Jun-2018 | 1 Day(s) | D-C | Suspected Adverse Event: As reported by the pet owner, Akiles, a male mixed breed cat of 2 years old and 5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, not in whole body), applied by the reporter 1 week ago (22 Jun 2018), for flea treatment. The pet was in good health prior to FL. The pet licked the product. One day after product application, the pet presented with paralysis and almost 'died'. Around 2 days after product application, the animal also presented pruritus, hair loss, anorexia and a change in its liver'. An unknown antibiotic was administered. The pet recovered on date not specified. SLOE cases reported on 18BR004439 to 18BR004444. PQC reported on 18BR004446. No further information is expected. |
| 28-Jun-2018 | UAE; 18BR004449; MG; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** FIPRONIL SPRAY;<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2017* | 28-Jun-2018* | 27 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, one male mixed breed cat of 7 years old (other signalment is unknown), was treated with FRONTLINE SPOT-ON (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter 'less than 30 days' (1 Jun 2018 - estimated date). Lack of efficacy is suspected because the pet remains with fleas. In addition, the number of fleas has increased. The environment has been treated with deltamethrin and FL has been applied monthly (first application was not provided - 1 Jan 2017 chosen at random). So, the reporter applied FRONTLINE SPRAY on 28 Jun 2018 (unknown lot, Jun 2018, topical, whole body), but the pet remained infested by fleas. Similar cases reported on 18BR004450, 18BR004472 and 18BR004473. PQC cases reported on 18BR004451 and 18BR004452. No further information is expected. |
| 28-Jun-2018 | UAE; 18BR004450; MG; Brazil | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 18.00 Month(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** FIPRONIL SPRAY;<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 28-Jun-2018* | 27 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, one male mixed breed cat of 18 months old (other signalment is unknown), was treated with FRONTLINE SPOT-ON (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter 'less than 30 days'(1 Jun 2018 - estimated date). Lack of efficacy is suspected because the pet remains with fleas. In addition, the number of fleas has increased. The environment has been treated with deltamethrin and FL has been applied monthly and first application was not provided - 1 Jan 2017 chosen at random. So, the reporter applied FRONTLINE SPRAY on 28 Jun 2018 (unknown lot, Jun 2018, topical, whole body), but the pet remained infested by fleas. Similar cases reported on 18BR004449, 18BR004472 and 18BR004473. PQC cases reported on 18BR004451 and 18BR004452. No further |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | information is expected. |
| 26-Jun-2018 | UAE; 18BR004453; SP; Brazil | **Species:** Canine **Breed:** Pug **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 24-Jun-2018 | 27-Jun-2018* | 3 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner via social media, Maike, a male Pug of 9 months old and 8 kg, received, for the first time, one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, base of skull and btw the shoulder blades), applied by the reporter 5 days ago (24 Jun 2018). The pet was in good health prior to FL and has no history of adverse reactions. Around 3 - 4 days after product application, the pet presented with application site lesion and some small lumps on the head. The vet prescribed omega 3 and Agemoxi®, but the dog was not treated yet. The vet has a high level of suspicion that the product caused this issue. The symptoms are still ongoing. A similar case was reported on 18BR004454. SLOE case was reported on 18BR004455. No further information is available. UPDATE 2 JUL 2018 - According to the vet, on 29 Jun 2018, Maike was taking to the vet clinic presenting moist dermatitis near the product application and close to the tail. She doesn't has a suspicion that FL has caused this reaction. The vet also prescribed Revolution®. No further information is expected. |
| 26-Jun-2018 | UAE; 18BR004454; SP; Brazil | **Species:** Canine **Breed:** Pinscher (Miniature) **Sex:** M **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 22-Jun-2018 | 25-Jun-2018* | 3 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner via social media, Jack, a male Pinscher of 2 years old and unknown weight, received, for the first time, one vial of FRONTLINE SPOT-ON (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by an unknown person 7 days ago (22 Jun 2018). The pet was in good health prior to FL and has no history of adverse reactions. On date not specified after product application, the pet presented with a lesion near the anus. The vet prescribed Crema 6A® and a soap for allergy. The vet has a high level of suspicion that the product may be the cause of this reaction. The current status of the animal is unknown. A similar case was reported on 18BR004453 and a SLOE case was reported on 18BR004455. No further information is available. |
| 26-Jun-2018 | UAE; 18BR004455; SP; Brazil | **Species:** Canine **Breed:** Pug **Sex:** M **Sex qualifier:** Unknown **Age:** 9.00 Month(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 24-Jun-2018 | 28-Jun-2018* | 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, Maike, a male Pug of 9 months old and 8 kg, received, for the first time, one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, base of skull and btw the shoulder blades), applied by the reporter 5 days ago (24 Jun 2018). Lack of efficacy is suspected because the pet has fleas. No more details were provided. SAE cases were reported on 18BR004453 and 18BR004454. This is the extent of the information available. |
| 29-Jun-2018 | UAE; 18BR004459; -; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown | N/A | 29-Jun-2018* | 2 Week(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female dog of unknown signalment, received one vial of FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter 2 weeks ago (15 Jun 2018 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. This is the extent of the information available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | to Company | | | | | |
| 29-Jun-2018 | UAE; 18BR004465; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 17 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 03-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Lisa Marry, a female medium crossbred dog of 3 years old and 17 kg, received one vial of FRONTLINE SPOT-ON DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 2 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas . In addition, the pet has flea allergy dermatitis. The environment has not been treated and it is unknown if FL has previously been applied. Similar cases reported on 18BR004466 and 18BR004467. Lisa Marry also had a reaction after product application (see case 18BR004468). No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004466; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** M **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 03-Jun-2018* | 1 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, Mascara, a male medium crossbred dog of 10 years old and 14 kg, received one vial of FRONTLINE SPOT-ON DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 2 Jun 2018, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated and it is unknown if FL has previously been applied. SLOE cases reported on 18BR004465 and 18BR004467. SAE case reported on 18BR004468. No further information is expected. |
| 29-Jun-2018 | UAE; 18BR004467; SP; Brazil | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 10-Jan-2017* | 9 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, one dog of unknown signalment received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Jan 2017 - chosen at random). The owner believed that FL didn't work. Details were not provided. SLOE cases reported on 18BR004465 and 18BR004466. SAE case reported on 18BR004468. This is the extent of the information available. |
| 29-Jun-2018 | UAE; 18BR004468; SP; Brazil | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 17 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 03-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner, Lisa Marry, a female medium crossbred dog of 3 years old and 17 kg, received one vial of FRONTLINE SPOT-ON DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 2 Jun 2018, for flea treatment. One day after product application, the dog started scratching herself and presented with application site reddening. The current status of the animal is unknown. SLOE cases reported on 18BR004465, 18BR004466 and 18BR004467. This is the extent of the information available. |
| 28-Jun-2018 | UAE; 18BR004472; MG; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** FIPRONIL SPRAY; **Route:** unknown **Was the product used** | 01-Jan-2017* | 28-Jun-2018* | 27 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 male mixed breed cats of unknown signalment, were treated with FRONTLINE SPOT-ON (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter 'less than 30 days' (1 Jun 2018 - estimated date). Lack of efficacy is suspected because the animals remained with fleas. The environment has been treated with deltamethrin. FL has been applied monthly and first application was not provided - 1 Jan 2017 chosen at random. So, the reporter applied FRONTLINE SPRAY on 28 Jun 2018 |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Unknown to Company | | | | | (unknown lot, Jun 2018, topical, whole body), but the animals also remained infested by fleas. Similar cases reported on 18BR004449, 18BR004450 and 18BR004473. PQC cases reported on 18BR004451 and 18BR004452. No further information is expected. |
| 28-Jun-2018 | UAE; 18BR004473; MG; Brazil | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 8 | 8 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** FIPRONIL SPRAY; **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Jan-2017* | 28-Jun-2018* | 27 Day(s) | D-D | Suspected Lack of Efficacy Claim: As reported by the pet owner, 8 female mixed breed cats of unknown signalment, were treated with FRONTLINE SPOT-ON (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter 'less than 30 days' (1 Jun 2018 - estimated date). Lack of efficacy is suspected because the animals remained with fleas. The environment has been treated with deltamethrin. FL has been applied monthly and first application was not provided - 1 Jan 2017 chosen at random. So, the reporter applied FRONTLINE SPRAY on 28 Jun 2018 (unknown lot, Jun 2018, topical, whole body), but the animals remained infested by fleas. Similar cases reported on 18BR004449, 18BR004450 and 18BR004472. PQC cases reported on 18BR004451 and 18BR004452. No further information is expected. |
| 17-May-2018 | UAE; 18CH000037; -; Switzerland | **Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** Unknown | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 07-Apr-2018 | 07-Apr-2018 | 10 minutes | D-A | Suspected Adverse Reaction: As reported by the attending vet, a cat, European Shorthair, male neutered, 10 years old, weight unknown, in a good health condition, was treated for prophylaxis, with FRONTLINE COMBO (BN and exp date unknown), dosage unknown, administered topically on an unknown site by the owner, on 7 Apr 2018. 10 minutes after the administration, the cat experienced foam from the mouth and died. The cat has previously received this product but there is no information about the dates of administration and the possible previous reactions. No information is available concerning concomittant administration on the same day of other products. The attending vet level of suspicion is unknown. Update 01 June 2018: necropsy results were provided. The cat is named Schrek, date of necropsy is 12 Apr 2018. It is reported that the cat had circulatory collapse, circulation failure 10 minutes after the administration and died. The animal was in good condition. Necropsy results yielded pulmonic, arterial hypertrophy of the media, slight bronchiolectasy, alveolar emphysema and a mild acute pneumonia of desquamation, storage of glycogen and fatty degeneration of the Ito cells of the liver, lymphozytic depletion (spleen). The examined animal showed neither macroscopic nor histological alterations, which would indicate the presence of a relevant underlying disease. The alterations in the lung are only minimal (feline asthma with a light, acute, inflammatory component). It is improbable that these alterations have led to the sudden death of the animal. The glycogen storage and the fatty degeneration of the Ito cells in the liver can be looked at as unspecific and do not have a clinical relevance.<br>An acute heart and circulation failure due to the application of the medicament can not be explained by the pathological findings, so that the reason of the sudden death of the animal remains unclear. |
| 11-Jun-2018 | UAE; 18CL000009; Santiago de Chile; Chile | **Species:** Canine **Breed:** Poodle (Standard) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) | - | - | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other | 02-Mar-2018 | 02-Mar-2018 | 0 Day(s) | D-E | On 22 May 2018, AH PVG Chile department received the following complaint:<br>As reported by owner, Lady, canine, poodle, female, 03 years old, 4 kg, neutered reproductive status, received FRONTLINE PLUS for small dogs, batch 036/15, expiry date Nov-2018, 1 topic pipette 0,67 ml administered by owner on 02/03/18 for flee treatment and Chimuelo, canine, poodle, male, 01 year old, 6 kg, intact |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Weight:** 4 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | reproductive status, received FRONTLINE PLUS for small dogs, batch 036/15, expiry date Nov 2018, 1 topic pipette 0,67 ml administered by owner on 02/03/18 for flee treatment also. Fleas decreased just by first week and thereafter fleas increased and have not disappeared up to date.<br>Owner reported the product doesn't work as it used to due to fleas reappearance even though he followed the directions (no bath 48 hrs before/ after). No other fleas treatment has been given to (L) and (C) by today.<br>Pet owner lives in a house with a small garden, partially cemented. (L) and (C) expends all day indoor and does not have contact with other pets. |
| 25-Jun-2018 | UAE; 18CZ000001; -; Czech Republic | **Species:** Canine<br>**Breed:** German Shepherd Dog<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 10.00 Month(s)<br>**Weight:** 30 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 06-Apr-2018 | 20-Apr-2018 | 2 Week(s) | D-E | Suspected LOE report: as reported by wholesaler, a female dog, Aria, German Sherperd, 10 months old, 30 kg weight, in good health condition, received FRONTLINE SPRAY 250 ML (BN P05603A, exp date Nov 2019) administered topically by owner on 6 April 2018 for anti tick protection. On 20 April 2018, 2 weeks after product administration, there were a lot of attached ticks that didn't detach. The wholesaler described a poor efficacy which started from the end of the second week continuouly. The product was used correctly according to the dog's owner. This is the extent of information available. Case linked with 18CZ000002. |
| 25-Jun-2018 | UAE; 18CZ000002; -; Czech Republic | **Species:** Canine<br>**Breed:** Staffordshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Year(s)<br>**Weight:** 27.000 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 06-Apr-2018 | 20-Apr-2018 | 2 Week(s) | D-E | Suspected LOE report: as reported by wholesaler, a female dog, Zira, Amstaff, 9 years old, 27 kg weight, in good health condition, received FRONTLINE SPRAY 250 ML (BN P05603A, exp date Nov 2019) administered topically by owner on 6 April 2018 for anti tick protection. On 20 April 2018, 2 weeks after product administration, there were a lot of attached ticks that didn't detach. The wholesaler described a poor efficacy which started from the end of the second week continuouly. The product was used correctly according to the dog's owner. This is the extent of information available. Case linked with 18CZ000001. |
| 06-Apr-2018 | UAE; 18DE000256; -; Germany | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** 13.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 02-Apr-2018 | 03-Apr-2018 | 1 Day(s) | D-D | As reported by the staff of a pharmacy a 13 year old unknown dog was treated with 1 pipette of an unknown FRONTLINE SPOT ON FOR DOGS (MAH comment: FRONTLINE SPOT-ON H 20 Germany 400081.01.00 Boehringer Ingelheim Vetmedica GmbH was chosen as best guess) on 2 Apr 2018 once topically by the animal owner. From the next day on the dog showed an intense tickly throat (coded as coughing). No more details. |
| 10-Apr-2018 | UAE; 18DE000271; -; Germany | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** PO-Oral<br>**Was the product used** | 03-Apr-2018 | 07-Apr-2018 | N/A | D-D | As reported by the animal owner a unknown Chihuahua-Mix was ´taking FRONTLINE since 3 Apr 2018´ (MAH comment: as no concrete product was given FRONTLINE SPOT ON H 10 was set as best guess. Off-label use according to given data: route (orally) and treatment protocol). On 7 Apr 2018 the owner noticed, that the dog showed ´altered mentality like reacting hectically to things´. Additionally the dog showed vomitus in irregular intervals ´since taking in the drug´. No more details. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **ok?:** No (Treatment / vaccination program not respected) | | | | | |
| 23-Apr-2018 | UAE; 18DE000305; -; Germany | **Species:** Canine **Breed:** Beagle **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 17.5 kg | 2 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 2017* | 2017* | N/A | D-D | As reported by the animal owner a 9 year old male neutered Beagle (17.5 kg body weight) was treated with FRONTLINE regularly and showed mild apathy from time to time after treatment (no more details). On 18 Apr 2018 this dog was treated once topically with 1 ampule of FRONTLINE SPOT ON H 20 (10-20 kg) by the animal owner for parasite control together with a partner animal. Oral intake was not noticed by the owner, licking the partner animal can be ruled out. The next day the dog showed apathy. On 21 Apr 2018 the owner noticed, that the dog was apathic, no longer jumping on the windowsill as usual and was putting less weight on the right hind limb (coded as lameness) while eating normally. There were neither swelling nor pain at the limb. No trauma was reported and the partner animal did not show any symptoms. No more details. |
| 24-Apr-2018 | UAE; 18DE000306; -; Germany | **Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 19-Apr-2018 | 21-Apr-2018* | 2 Day(s) | D-C | As reported by the staff of a pharmacy the own 4 year old male neutered European cat (6 kg body weight) was administered once topically 1 ampule of FRONTLINE SPOT ON K because of suspected flea infestation on 19 Apr 2018. About 2 days later the cat showed abnormal behavior (like hiding, refused being touched and running around from time to time) and showed twitching of the paws (coded as twitching). The cat goes outside, too and it is very difficult to examine it. Oral intake was not observed. On 27 Apr 2018 the owner called again and reported, that the cat was brought to a vet and an injury on the cat´s back was found, which was likely been caused by a trauma. No more details. |
| 13-Apr-2018 | UAE; 18DE000350; -; Germany | **Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 41 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | 2017* | Apr-2018* | N/A | D-D | SLEE: As reported by the staff of a pharmacy the own male Labrador Retriever (propably slightly over 40 kg body weight) was treated once topically with FRONTLINE SPOT ON H 40 in 2017. On 4 Apr 2018 the dog was treated again once topically with 1 ampule by the animal owner for tick prophylaxis. Unknown time later there were alive ticks walking around on the dog after each walk, some ticks already attached and feeding. The owner has regularly been collecting the ticks off the dog (unknown intervals). Last year the owner noticed, that the ticks were moving slower and were falling down on their own, but this year the product seemed to be less effective. According to the owner the product was applied correctly and the dog was not washed. No more details. |
| 16-Apr-2018 | UAE; 18DE000351; -; Germany | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 2 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 2015* | 16-Apr-2018* | 8 Day(s) | D-D | SLEE: As reported by the animal owner a unknown cat (about 2 kg body weight) has been treated with unknown FRONTLINE SPOT ON (MAH comment: FRONTLINE SPOT ON K was set as best guess) since several years. On about 8 Apr 2018 the cat was treated once topically on the neck with 1 ampule by the animal owner. 8 days later there were 2 ticks on the cat. No more details. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 17-Apr-2018 | UAE; 18DE000353; -; Germany | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 2015* | 2017 | N/A | D-D | SLEE: The reporting animal owner has been treating their cats since several years with FRONTLINE. Since last year the cats seemed to have more ticks. On 4 Apr 2018 one of them, a male cat (no more details) was treated with unknown FRONTLINE (no more details; MAH comment: FRONTLINE SPOT ON K was set as best guess). On 16 Apr 2018 there were 2 ticks on the cat, on 17 Apr 6 ticks. No more details |
| 22-Apr-2018 | UAE; 18DE000354; -; Germany | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 2006* | Apr-2018* | unknown | D-E | SLEE: As reported by the animal owner they use FRONTLINE for their unknown cat since 12 years without any problems. Last week there were 2 ticks on the cat despite correct dosage and frequency (no more details). (MAH comment: as no concrete product was given FRONTLINE SPOT ON K was set as best guess.) |
| 30-Apr-2018 | UAE; 18DE000358; -; Germany | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 22-Apr-2018 | 29-Apr-2018 | 1 Week(s) | D-D | SLEE: as reported by the animal owner a unknown male cat was treated with FRONTLINE once topically in the neck on 22 Apr 2018 by the animal owner for tick control. On 29 Apr there were 3 feeding ticks and 4 moving ticks on the cats neck. No more details. (MAH comment: as no concrete product was given FRONTLINE SPOT ON K was set as best guess) |
| 04-May-2018 | UAE; 18DE000359; -; Germany | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 2016* | 2018 | 0 Day(s) | D-E | SLEE: as reported by the animal owner a unknown male cat has been treated with FRONTLINE for years. This year, despite application according to the label (no more details) the product seems to be less effective and´ the cat brings home at least 3 ticks a week´. (MAH comment: as no concrete product was given FRONTLINE SPOT ON K was set as best guess) |
| 18-Apr-2018 | UAE; 18DE000360; -; Germany | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used** | 2018* | 2018* | 0 Day(s) | D-E | SLEE: As reported by the animal owner there is a flea infestation in a household with unknown dogs and cats (MAH comment: as no concrete numbers of animals were given 1 animal per product was set as best guess). An unknown dog was treated twice with FRONTLINE SPOT ON H 10 (2-10 kg) by the animal owner on unknown date and intervalls. The other animals were treated twice, too (see linked cases DEu-BIAHPV1P-18DE000365 and DEU-BIAHPV1P-18DE000366). Despite treatment of the environment (unknown fogger, cleaning) there were still fleas on |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **ok?:** Unknown to Company | | | | | the animals at the time reporting. The reporter used the product in the past for several years without having problems. Now the product seemed to smell differently and to be less effective. No more details. |
| 18-Apr-2018 | UAE; 18DE000365; -; Germany | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 2018* | 2018* | N/A | D-E | SLEE: As reported by the animal owner there is a flea infestation in a household with unknown dogs and cats (MAH comment: as no concrete numbers of animals were given 1 animal per product was set as best guess). An unknown dog was treated twice with FRONTLINE SPOT ON H 20 (10-20 kg) by the animal owner on unknown date and intervalls. The other animals were treated twice, too (see linked cases DEU-BIAHPV1P-18DE000360 and DEU-BIAHPV1P-18DE000366). Despite treatment of the environment (unknown fogger, cleaning) there were still fleas on the animals. The reporter used the product in the past for several years without having problems. Now the product seemed to smell differently and seemed to be less effective. No more details. |
| 18-Apr-2018 | UAE; 18DE000366; -; Germany | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 2018* | 2018 | N/A | D-E | SLEE: As reported by the animal owner there is a flea infestation in a household with unknown dogs and cats (MAH comment: as no concrete numbers of animals were given 2 cats was set as best guess). The cats were treated twice with FRONTLINE SPOT ON K by the animal owner on unknown date and intervalls. The other animals were treated twice, too (see linked cases DEU-BIAHPV1P-18DE000360 and DEU-BIAHPV1P-18DE000365). Despite treatment of the environment (unknown fogger, cleaning) there were still fleas on the animals. Additionally one male cat had one thick tick on 17 Apr 2018. The reporter used the product in the past for several years without having problems. Now the product seemed to smell differently and to be less effective. No more details. |
| 07-May-2018 | UAE; 18DE000367; -; Germany | **Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 14-Apr-2018* | 15-Apr-2018* | N/A | D-E | SLEE: As reported by the staff of a pharmacy a 7 year old female European cat (body weight: 5 kg) was treated once topically in the neck with 1 ampule FRONTLINE SPOT ON K (batch no. R20811AW, expiry date 04/2020) by the animal owner for parasite control on about 14 Apr 2018. The cat is living mostly outdoors and is only coming inside to feed and play several times a day. However, the owner noticed about 5-10 living ticks on the cat each time she has seen the cat even 2 weeks after the administration of Frontline. No more details. |
| 16-May-2018 | UAE; 18DE000369; -; Germany | **Species:** Feline **Breed:** Persian (No Further Description) **Sex:** M **Sex qualifier:** - **Age:** 14.00 Month(s) **Weight:** 5.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** other **Was the product used ok?:** Unknown to Company | 18-Apr-2018 | 20-Apr-2018* | N/A | D-D | DE-BVL-2018-04621: Reason for treatment: prophylaxis. According to the attending veterinarian a male cat (Persian- main Coon mixed breed) with 14 month of age and weighting 5.1 kg was treated with Frontline Spot on on 18th April 2018. Approximately 48 hours later there was a dermatitis in neck area and alopecia, bacterial infection suspected due to response on therapy with Duphamox LA four treatments with 2 days apart, healing of dermatitis, skin at the moment without hair, but nonirritated. Further information received from Authority: lot number uncertain according to vet. |
| 10-May-2018 | UAE; 18DE000370; -; Germany | **Species:** Canine **Breed:** Canine (unknown) | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG | 2018* | 2018* | N/A | D-D | SLEE: as reported by the animal owner an unknown dog (30 kg body weight) was treated once topically with 1 ampule of FRONTLINE (20-40 kg) by the animal owner (MAH comment: as |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 30 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | the given FRONTLINE product was not further specified, FRONTLINE SPOT-ON HUND L was chosen by best guess). The dog was neither bathed nor went swimming. 3 weeks later the dog had one tick near the eye. MAH comment: this owner reported also an adverse event the cats of her sister had after the use of FRONTLINE. This case is reported separately in the linked case DEU-BIAHPV1P-18DE000372. |
| 13-May-2018 | UAE; 18DE000371; -; Germany | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 9.000 kg* | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 29-Apr-2018* | 13-May-2018* | 2 Week(s) | D-D | SLEE: as reported by the animal owner two dogs (about 9 kg body weight, no more details) were treated ´with the appropriate dose´ once topically with 1 ampule unknown Frontline on about 29 Apr 2018 (MAH comment: as no concrete product was given FRONTLINE SPOT ON H10 2-10 kg was set by best guess). The whole product was given directly on the skin and the dogs didn´t go into water the next 48 hours. Two weeks later both dog had several ticks (still alive). No more details. |
| 10-May-2018 | UAE; 18DE000372; -; Germany | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 3 | 3 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 2018* | 2018* | N/A | D-D | A dog owner reported via email that the 3 cats of her sister had been treated with FRONTLINE (MAH comment: as the given FRONTLINE product was not further specified, FRONTLINE SPOT ON KATZE was chosen by best guess). Not even 4 weeks later the cats had ticks. MAH comment: the dog owner reported also an adverse event for her own dog after the use of FRONTLINE, which is reported separately in the linked case DEU-BIAHPV1P-18DE000370. |
| 17-May-2018 | UAE; 18DE000376; -; Germany | **Species:** Feline<br>**Breed:** European<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 13.00 Year(s)<br>**Weight:** 4.5 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 26-Apr-2018* | 27-Apr-2018* | N/A | D-D | A pharmacy technician reported that a 13-year-old, male neutered European Shorthair cat (body weight: about 4.5 kg) had been treated with 1 pipette FRONTLINE SPOT ON KATZE once topically due to a flea infestation on about 26 Apr 2018. About one day later the cat showed dermatitis at the application site. The cat was therefore presented to the vet who administered a not further specified spray/ointment. Until 17 May 2018 signs improved, but a mild reddening was still visible. Further information received: no concomitant diseases are known for this cat. |
| 20-May-2018 | UAE; 18DE000382; -; Germany | **Species:** Canine<br>**Breed:** Border Collie<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** -<br>**Weight:** 24 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / | 10-Mar-2018* | 10-Mar-2018* | N/A | D-D | As reported by the animal owner a male intact Bordercollie-Muensterlaender crossbred dog (24 kg body weight) was treated topically for parasite prophylaxis with 1 ampule FRONTLINE SPOT ON H 40 (batch no. P20621AR, expiry date Apr 2019) on 10 Mar, 26 Mar and 09 May 2018 (off-label intervals) by the animal owner. About 2 days after the first application the dog showed pruritus all over the body for about 2 days. After the second and third treatment the dog showed pruritus the following day, which was self limiting. The last time the pruritus was also getting better without treatment, but was still not as well as before administration. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | vaccination program not respected) | | | | | |
| 21-May-2018 | UAE; 18DE000383; -; Germany | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** No (Route not indicated / recommended) | 2018* | 2018* | 0 Day(s) | D-D | As reported by the animal owner via the FRONTLINE homepage an unknown cat has been treated with ´the Spot On against ticks and fleas´. (MAH comment: as no concrete product was given this case was entered as worst case for Frontline. So FRONTLINE SPOT ON K was set as best guess). Sometimes, as the cat was licking the fur there might be oral intake of ´1-2 drops´of the product and the cat showed intense hypersalivation´ afterwards´. No more details despite attempt to get more information. |
| 22-May-2018 | UAE; 18DE000385; -; Germany | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 18-May-2018 | 18-May-2018 | N/A | D-D | A pharmacist reported that her own 10-year-old, male neutered cat had suffered from pruritus. On 18 May 2018 the cat was then treated with 1 pipette FRONTLINE KATZE once topically in the neck for parasite prophylaxis (MAH comment: as the given FRONTLINE cat product was not further specified, FRONTLINE SPOT-ON KATZE was chosen by best guess). 15 minutes after the application the cat showed marked salivation and has appeared 'absent' since then (not as severe as apathy according to the owner), but has shown normal appetite. The owner also reported that a building in the neighbourhood is currently demolished and renovated, and that she cannot exclude that the cat had got into contact with toxic substances there. The further outcome is unknown. Further information received: the cat had already been treated with this FRONTLINE product in the past. |
| 24-May-2018 | UAE; 18DE000389; -; Germany | **Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** Fluid to flush the cat's eye; **Route:** Ophthalmic **Was the product used ok?:** No (Route not indicated / recommended) | 24-May-2018 | 24-May-2018 | shortly thereafter | D-C | A vet reported that a 1-year-old, female neutered European Shorthair cat (born on 12 May 2017) had been treated by the owner with 1 pipette FRONTLINE SPOT-ON KATZE once for parasite prophylaxis on 24 May 2018. During the application a splatter of FRONTLINE splashed into the cat's left eye. The cat was therefore immediately presented to the vet and the eye was flushed. During flushing the cat developed marked malaise. However, the conjunctiva was only mildly reddened and a fluorescein test was negative. Treatment with hyaluronan eye drops was started. The further outcome is unknown. |
| 06-May-2018 | UAE; 18DE000395; -; Germany | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Treatment / vaccination | 2017* | 2017* | N/A | D-E | SLEE: as reported by the animal owner they used FRONTLINE in the past und stopped it because it seemed to be less effective (no more details, 2017 was set by best guess). Now they moved into a region with a lot of ticks about half a year ago and therefore 2 unknown dog were treated ´again´with unknown FRONTLINE every 4 weeks (MAH comment: as no concrete product was given FRONTLINE SPOT ON H 20 was set as best guess). Last administration was on about 30 Apr 2018, which was only 2 weeks after the previous administration. On 6 May the owner noticed 7 ticks, 10 days before 5 ticks on the dogs. No more details. |

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| | | | | | | program not respected) | | | | | |
| 26-Apr-2018 | UAE; 18DE000396; -; Germany | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 12-Apr-2018* | 18-Apr-2018 | N/A | D-D | SLEE: As reported by the staff of a pharmacy 2 cats (8 years old, female neutered, ´small´, according to pharmacy less then 5 kg) were treated twice topically with 1 ampule of FRONTLINE SPOT ON K each cat by the animal owner because of flea infestation on about 12 Apr 2018. There is contradictory data about when the second dose was given (details about 2 weeks apart, but also after 3 weeks). On 18 Apr 2018 the cats still had fleas. No more details. |
| 16-May-2018 | UAE; 18DE000397; -; Germany | **Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 2015* | 2018 | 0 Day(s) | D-E | SLEE: as reported by the animal owner a Jack Russell Terrier has been treated with 1 ampule of FRONTLINE SPOT ON H 10 for years. This year after 2 to 3 weeks the dog had ticks, whereby in the last years this was after 5-6 weeks. No more details. |
| 18-May-2018 | UAE; 18DE000401; -; Germany | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 04-May-2018* | 04-May-2018* | N/A | D-E | SLEE: as reported by the animal owner a unknown cat was treated with unknown FRONTLINE (MAH comment: FRONTLINE SPOT ON K was set as best guess) against ticks 14 days ago but ´unfortunately it was not successful´. No more details. |
| 25-May-2018 | UAE; 18DE000404; -; Germany | **Species:** Feline **Breed:** European **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 4 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 02-May-2018* | 04-May-2018* | 2 Day(s) | D-E | SLEE: as reported by the staff of a pharmacy a unknown European cat (about 4 kg body weight) was treated once topically in the neck with 1 ampule of FRONTLINE SPOT ON K (batch no. R20107AW) on 2 or 3 May 2018. The cat was not washed within the next 2 days. The cat goes outside regularly and unknown time after administration the cat had several ticks per day. No more details. |
| 01-Jun-2018 | UAE; 18DE000407; -; Germany | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products | May-2018* | May-2018* | N/A | D-E | SLEE: as reported by the staff of a pharmacy an animal owner bought FRONTLINE SPOT ON H 40 on 19 Apr 2018. Date of administration unknown. Unknown time later the dog had ticks. Same reporter as DEU-BIAHPV1P-18DE000408, cases are linked. No more details. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Age:** -<br>**Weight:** Unknown | | | | **Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | |
| 01-Jun-2018 | UAE; 18DE000408; -; Germany | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | May-2018* | May-2018* | N/A | D-E | SLEE: as reported by the staff of a pharmacy an animal owner bought FRONTLINE SPOT ON K (batch no R20428AW, expiry date 01/2020) on 19 Apr 2018. Date of administration unknown. Unknown time later the cat had ticks. Same reporter as DEU-BIAHPV1P-18DE000407, cases are linked. No more details. |
| 04-Jun-2018 | UAE; 18DE000436; -; Germany | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 2016* | May-2018* | N/A | D-E | SLEE: As reported by the animal owner via email an unknown dog was treated regularly with FRONTLINE SPOT ON H 10 (PZN 0662876, expiry date 05 2020) without problems for years. Now unknown time after administration the dog had ticks. No more details. |
| 04-Jun-2018 | UAE; 18DE000438; -; Germany | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | May-2018* | May-2018* | N/A | D-E | SLEE: As reported by the animal owner via email a unknown dog was treated with unknown FRONTLINE SPOT ON (MAH comment: as no concrete product was given FRONTLINE SPOT ON H20 was set by best guess) ´according to body weight´. Despite administration the dog had ticks. No more details. |
| 14-Jun-2018 | UAE; 18DE000445; -; Germany | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** 15.00 Month(s)<br>**Weight:** 6.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** PO-Oral<br>**Was the product used ok?:** No (Species not indicated / recommended) | 13-Jun-2018 | 13-Jun-2018* | during the night | D-C | As reported by the animal owner a 15 months old small crossbred dog (6.7 kg body weight, no more details) was licking intensively the application site shortly after the partner-cat was treated once topically with 1 ampule of FRONTLINE SPOT ON K on 13 Jun 2018 at about 2 p.m. (off-label dog: route and species). On about 7 a.m. the next morning the owner noticed, that the dog had vomited during the night and showed mild apathy still ongoing at the time reporting. The dog was brought to a vet. An x-ray was done and the vet diagnosed ´vomitus´. The dog was treated with 0.5 ml Buscopan, 2 ml Catosal, 1 ml Vit.B12, 0.6 ml Hexadreson (50mg/ml), 0.5 ml Emepril and Bariumsulfat 10 ml. |
| 14-Jun-2018 | UAE; 18DE000447; -; Germany | **Species:** Canine<br>**Breed:** Canine (unknown) | 3 | 1 | 0 | **Product used:** FIPRONIL SPRAY | 2018* | 2018* | N/A | D-C | As reported by the animal owner unknown dogs (MAH comment: as no concrete number of exposed animals was given, 3 was set as best guess) were treated ´according to the label´with |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | **Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | FRONTLINE SPRAY 500 ml on unknown date. One of them showed swelling of the skin ´wherever the skin was in contact with the product, which was the whole body despite nose and mouth region´ unknown time later. Additionally the dog showed reddening of the skin at unknown location and was uncomfortable being touched (coded as increased skin sensitivity) while eating and moving normally. The most intense swelling was observed at the ears. 4 days later there was´ no more swelling and no lasting damages´. No more details. |
| 19-Jun-2018 | UAE; 18DE000451; -; Germany | **Species:** Feline<br>**Breed:** European<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** Emodepsid; Cerenia; Phenobarbital; Infusion; Loxiran (kein TAM);<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Others) | 12-Jun-2018 | 13-Jun-2018 | 1 Day(s) | D-B | As reported by the attending vet a 7 year old female neutered European cat (6 kg body weight) was treated once topically with 1 ampule of FRONTLINE COMBO SPOT ON FOR CATS (batch no. R40510, expiry date 04/2020) by the animal owner on 12 Jun 2018 for parasite control. As the cat was moving during application the product was not applied between the shoulder blades ( off-label application), so it is unknown if the cat was able to lick some of it. The next day about noon the cat showed intense hypersalivation and was treated with Emodepsid and Cerenia in another vet practice. In the afternoon the cat showed ´seizures´ and was hospitalized and treated with Phenobarbital (15 mg BID) and infusion. Blood parameters were within normal range despite eosinophilia. On 18 Jun 2018 the cat was brought to the reporting vet who send it to a neurologist. This specialist advised to run an MRT, which was not done so far and the cat came back to the reporting vet practice. According to the owner the cat still showed about 20 ´seizures´per day with a duration of 20-30 seconds each. The vet described the seizures: initially mewing, then restlessness, erecting the tail hair (coded as behavioral disorder NOS), walking in circles to the left, hissing (coded as vocalization) and hypersalivation, sometimes urinating. Additional information: the cat goes outside regularly and was treated with Frontline Combo for several times before without any problems, there is no epilepsy in the medical history of the cat and no other drugs were given concomitantly. The blood work (unknown date) was unremarkable despite increased CK, elevated triglycerids and low cholinesterase (coded as abnormal test result) (MAH comment: as no concrete date of blood work was given 22 Jun 2018 was set as best guess). Unfortunately the blood sample arrived in the lab one day too late. On 25 Jun the cat was still treated with 15 mg Phenobarbital BID and since 22 Jun the cat did not show any more seizure. The vet called |
| 22-Jun-2018 | UAE; 18DE000458; -; Germany | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** 2.50 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 2018* | 2018* | N/A | D-D | As reported by the staff of a pharmacy a unknown 2.5 years old dog was treated with FRONTLINE SPOT ON L and unknown time later showed generalized hair loss. No more details. |
| 25-Jun-2018 | UAE; 18DE000460; -; Germany | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg) | 3 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products** | 11-Jun-2018* | 18-Jun-2018* | 1 Week(s) | D-D | As reported by the animal owner 3 dogs were treated with FRONTLINE: One of them, a 6 year old female intact mixed breed dog from Greece (20 kg body weight) was treated once topically with one ampule of FRONTLINE SPOT ON H 40 on about 11 Jun |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 20 kg | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | 2018 by the animal owner. About 1 week later the dog showed intense pruritus at the abdomen and inguinal, still ongoing at the day reporting. No reactions at the application site, despite that it is difficult to see the skin, because the dog has a long hair coat. The dog was treated with FRONTLINE before without any problems. |
| 26-Jun-2018 | UAE; 18DE000467; -; Germany | **Species:** Feline<br>**Breed:** European<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 12.00 Year(s)<br>**Weight:** 4.5 kg | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 2017* | 20-Jun-2018* | 4 Day(s) | D-C | As reported by the animal owner 2 cats were treated regularly every 4-6 weeks with FRONTLINE COMBO SPOT ON FOR CATS. A 12 year old female neutered European cat (4.5 kg body weight) was accidently treated in a 2 weeks interval (off-label: protocol): on 31 May 2018 and 16 Jun 2018 the cat was treated once topically with 1 ampule of FRONTLINE COMBO SPOT ON FOR CATS (batch no. M40708FX, expiry date Apr 2018-off-label:expired!) by the animal owner for tick prophylaxis. On about 20 Jun 2018 the owner noticed, that the cat showed head tremor to the left and twitching the paws while being calm. Additionally the cat was licking the front paws more intensely as usual and was running around from time to time (coded as hyperactivity) while being conscious. The cat is known to have ´kidney problems´ treated with homeopathics (Solidago comp. SID and Rhus Toxicodenron BID). The partner cat (9 years old, 3.5 kg body weight) was also treated but showed no symptoms. Both cats were going outside regularly. The owner wanted to wait for some more time before going to the vet. No more details. |
| 27-Jun-2018 | UAE; 18DE000475; -; Germany | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 15 | 15 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 16-May-2018* | 16-May-2018* | N/A | D-E | SLEE: as reported by the animal owner 15 dogs (up to 7 kg body weight, no more details) were treated because of flea infestation: the owner bought 2 bottles of FRONTLINE SPRAY 500 ml on the 16 May 2018 and 11 Jun 2018 and administered it ´probably shortly after´. The dogs were sprayed ´until the fur was really wet´, so dose is unknown and it is unknown if the product was applied directly on the skin as labeled. There was no treatment of the environment and ´even after the second application after about 4 weeks the dogs and owner still were suffering from flea bites´. The owner refused to give more information. |
| 28-Jun-2018 | UAE; 18DE000476; -; Germany | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 10.00 Year(s)<br>**Weight:** 27 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jun-2018 | 18-Jun-2018* | 2-3 Day(s) | D-E | SLEE: as reported by the animal owner a 10 year old male intact Labrador (27 kg body weight in good general condition) was treated once topically on the skin on multiple locations on the neck and back with 1 ampule of FRONTLINE SPOT ON H 40 on 1 Jun 2018 and 16 Jun 2018 (off-label: treatment protocol, incorrect administration) by the animal owner for tick treatment. The dog was not washed within the next 2 days. The dog was controlled for ticks every 2-3 days and about 2-3 days (contradictory data: 2-3 or 5 days) after the last administration the owner noticed still alive tick at the application site. |
| 29-Jun-2018 | UAE; 18DE000484; | **Species:** Canine<br>**Breed:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT | 28-Jun-2018 | 28-Jun-2018 | a few hours | D-D | As reported by the attending vet an animal owner called the vet practice: a male Dachshund (9.8 kg body weight, no more details) |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | -; Germany | Dachshund<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 9.8 kg | | | | ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | was administered once topically ´probably one ampule´of FRONTLINE SPOT ON 2-10 kg by the animal owner on 28 Jun 2018. It is unknown, if the product was applpied correctly. The owner reported to the vet, that a few hours later (MAH comment: 2 hours were set as best guess) the dog ´was acting crazy´, was attacking the owner (coded as aggression) and was walking in circles while eating, drinking and being responsive normally. The owner planned to wash the dog with Shampoo for decontamination. The vet did´t see the dog and refused to give more information. |
| 08-May-2018 | UAE; 18DK000039; -; Denmark | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 15-Nov-2017 | 16-Nov-2017 | 1 Day(s) | D-B | A pharmacist reported that an owner of a 2 years old female domestic cat, weight 3 kg had said that her cat had developped seizure on the 16-NOV-2017 at midnight after administration of Frontline (unspecified product) in the neck on the 15-NOV-2017 at 8 o'clock in the evening. The cat was crawling, shaking and was lame in hindpart for approximately 1 day. The reaction declined over approximately one day and the cat fully recovered. The owner gave the cat fluid and wrapped the cat in a blanket. It is unknown if veterinarian was consulted. The cat had received the product before without reacting and had no previous reported incidence of reactions to medicines. |
| 20-Jun-2018 | UAE; 18DK000050; -; Denmark | **Species:** Canine<br>**Breed:** French Bulldog<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | Jun-2018* | Jun-2018* | N/A | D-D | It was briefly reported by owner via social media on the 20-JUN-2018 that her French Bulldog of unknown age, sex, weight and health status had been given Frontline on an unknown date, product, strength and dose. On an unknown date the dog had alopeci and redness in an unspecified part of the dog. |
| 24-Apr-2018 | UAE; 18ES000327; Gerona; Spain | **Species:** Canine<br>**Breed:** Canine Other<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 17-Apr-2018* | 22-Apr-2018* | 5 Day(s) | D-D | Suspected LOE: As reported by the pet owner, an approximately 3 years old, male crossbred dog received Frontline Spot On dog, topical route, administered by pet owner between 17th or 18 th Apr 2018 (exact date unknown) for flea and tick treatment. Pet owner commented that have not bathed the dog since they applied Frontline. 5 or 6 days after product administration (exact date unknown), the dog had fleas and ticks. The dog also wore an antiparasitic collar (unknown brand) but the pet owner suspected of a lack of efficacy. It was the first time the dog received Frontline Spot On dog. The dog lived in the field with other farm animals and cats. The cats were under treatment with Frontline cats (specific type unknown). |
| 26-Apr-2018 | UAE; 18ES000328; -; Spain | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** F<br>**Sex qualifier:** Unknown | 1 | 1 | 1 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** Telmin;<br>**Route:** Topical / | 26-Apr-2018 | 26-Apr-2018 | 0 Day(s) | D-A | Suspected Adverse Event: As reported by the attending vet, a 2 month-old Retriever Labrador female dog received FRONTLINE SPRAY (batch number unknown) topically administered by the owner at home on 26APR2018 for fleas and tick treatment. She had been treated with Telmin and an antiparasitic bath on 24APR2018. After product administration the animal experienced |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Age:** 2.00 Month(s)<br>**Weight:** Unknown | | | | Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | trembling and falling. She was taken to the clinic and the attending vet thought about intoxication. The animal was like absent. Auscultation was correct. The animal was treated with atropine and corticoids, and one minute later the animal collapsed and died. |
| 08-May-2018 | UAE; 18ES000382; -; Spain | **Species:** Canine<br>**Breed:** Schnauzer (Miniature)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 2.50 Month(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Others) | 11-Apr-2018* | 11-Apr-2018* | N/A | D-B | Suspected Adverse Event: As reported by the attending vet, a 2.5 month-old Schnauzer (Miniature) male dog (Maki) received FRONLTINE SPRAY (batch number unknown) topically administered by the animal owner once a week for 3 weeks (three times) in APR2018 for prevention. The animal had been experiencing seizures (convulsion, drooling and paddling) during this time, and even less than one week after the end of product administration the animal continued with some epileptic seizures. They lasted for about 2 minutes and were not treated. Bile acid test was performed and showed normal results, thus, portosystemic shunt was ruled out. On 10MAY2018 the animal had not had any seizure again. The attending vet does not rule out that he sucked the other puppy that lives with him. |
| 24-May-2018 | UAE; 18FI000018; -; Finland | **Species:** Feline<br>**Breed:** Domestic Mediumhair (Crossbred)<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 3.00 Year(s)<br>**Weight:** 4.78 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 19-Apr-2018 | 19-Apr-2018 | <=1 hour | D-C | FI-Fimea-20180144:<br>Suspected AE: 3 years old domestic cat, male, treated with Frontline for tick prevention.<br>About one hour after application the cat was nauseous and started to drool strongly. The cat had some balance problems, difficulty to eat and to drink. The cat had been also listless. Findings at a vet clinic about week later: drooling long chewy saliva, dehydration and painful mouth. The cat was sedated and prominent erosive changes found in the cat's tongue. Supportive treatment was given: fluids, opioid and NSAID, medical charcoal, gastro protective medication and the cat was washed. Fully recovered. Later it came out that in the nearby of the owner and the area where the cat is freely moving is a laundry service place. It cannot be sure to say if the reaction is due to Frontline or some other chemical substance or both. |
| 27-Jun-2018 | UAE; 18FI000037; -; Finland | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 9.00 Year(s)<br>**Weight:** 30 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 02-May-2018 | 03-May-2018* | N/A | D-C | The app. 30 kg, 9 years old female labrador was treated with Frontline vet (large dog, batch no M23005) topically on 02.05.2018 and again on 30.05.2018. Approximately after 1 day, the dog got pruritus, the dog was very sensitive to touching and started to scratch itself after touching. The dog has also gotten some dyspnea and tachypnea attacks for 30 seconds at a time (the owner described them as human asthma attack). The attacks have occurred several times a week until a week before reporting, when they seem to have stopped. The dog has no previous heart or lung diseases or problems. It is unknown if the dog has been treated. |
| 06-Apr-2018 | UAE; 18FR000482; -; France | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** No | 01-Apr-2018* | 01-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the animal's owner, a female Chihuahua dog, received FRONTLINE (product unsubstantiated) (Batch and exp. date: unknown) administered by the owner on an unknown date (01 APR 2018 was chosen by default). After product administration (unknown time to onset), the animal experienced a reaction (unspecified coded as Uncoded sign in VEDDRA) and blood in the faeces. The animal was seen by a vet (unknown) who confirmed that the clinical signs were due to an overdose of Frontline. No further information was available at the time of this report. Off-label use: overdose. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | (Overdose) | | | | | |
| 18-Apr-2018 | UAE; 18FR000530; -; France | **Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Not applicable **Age:** 13.50 Year(s) **Weight:** 3.5 kg | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 12-Apr-2018 | 13-Apr-2018 | 1 Day(s) | D-C | FR-ANMV-18 CPVL 00564: D0 evening: 2 European cats were administered with FRONTLINE COMBO SPOT-ON CHAT, as usual. D1 morning: one cat displayed ataxia, trembling, areflexive mydriasis, amaurosis. Duration of reaction: < or = 6 hours. Duration of reaction (precision): Ongoing (a few hours). Reason for treatment: Preventive. Outcome of SAR: Unknown. FRONTLINE COMBO SPOT-ON CHAT () : 1 pipette/cat; duration: Once; onset time: < 12H. |
| 17-Apr-2018 | UAE; 18FR000534; -; France | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** - **Age:** - **Weight:** 2.4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Overdose) | 01-Apr-2018* | 03-Apr-2018* | 2 Day(s) | D-D | Suspected Adverse Event: As reported by the attending vet, a dog (unknown signalment) received one pipette of FRONTLINE COMBO SPOT ON CHIEN L (BN and exp. date: unknown) administered by DVM on an unknown date (01 APR 2018 was chosen by default). 48 hours after product administration, the animal experienced vomiting. No further information was available at the time of this report. Note: it was reported that the animal had had the same reaction after a previous administration of the product (unknown date). Off-label use: overdose. |
| 23-Apr-2018 | UAE; 18FR000550; -; France | **Species:** Canine **Breed:** Tibetan Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 10.00 Year(s) **Weight:** 12.000 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** - | 23-Mar-2018 | 23-Mar-2018* | N/A | D-D | Suspected Adverse Event: As reported by the animal's owner, Zonzon, a 10-year-old female Tibetan Terrier dog, 12 kg, received 3 pipettes of FRONTLINE SPOT-ON CHIEN M (Batch: P21417AX, Exp. date: 30 SEP 2019) administered between the shoulders and at two different sites on the back by the owner on 23 MAR, 06 APR and 16 APR 2018 because of fleas seen on the animal. After product administration (unknown time to onset), the animal experienced scratching and slight irritation. At the time of this report, the animal was still scratching itself. The owner planned to go back to the vet in the next few days. This case is linked with the cases 18FR0551 and 18FR0552: similar non-serious AE in two other dogs from the same household after administration of FRONTLINE SPOT-ON CHIEN. Note: this case was considered as an adverse reaction and not as a SLOE since the presence of fleas was not reported. |
| 23-Apr-2018 | UAE; 18FR000551; -; France | **Species:** Canine **Breed:** Tibetan Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 11.000 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** - | 23-Mar-2018 | 23-Mar-2018* | N/A | D-D | Suspected Adverse Event: As reported by the animal's owner, Dridri, a 5-year-old female Tibetan Terrier dog, 11 kg, received 3 pipettes of FRONTLINE SPOT-ON CHIEN M (Batch: P21417AX, Exp. date: 30 SEP 2019) administered between the shoulders and at two different sites on the back by the owner on 23 MAR, 06 APR and 16 APR 2018 because of fleas seen on the animal. After product administration (unknown time to onset), the animal experienced scratching and slight irritation. At the time of this report, the animal was still scratching itself. The owner planned to go back to the vet in the next few days. This case is linked with the cases 18FR0550 and 18FR0552: similar non-serious AE in two other dogs from the same household after administration of FRONTLINE SPOT-ON CHIEN. Note: this case was considered as |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | an adverse reaction and not as a SLOE since the presence of fleas was not reported. |
| 23-Apr-2018 | UAE; 18FR000552; -; France | **Species:** Canine **Breed:** Tibetan Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** 10.000 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** Vetmedin pimobendan chewable 2.5 mg DCP; CARDALIS 2.5; HOMEOPATHY (unspecified); **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 23-Mar-2018 | 23-Mar-2018* | N/A | D-D | Suspected Adverse Event: As reported by the animal's owner, Fifi, a 14-year-old female Tibetan Terrier dog, 10 kg, with heart problems (unspecified) and stones (unspecified type and location) received 3 pipettes of FRONTLINE SPOT-ON CHIEN S (Batch: R20411AX, Exp. date: JAN 2020) administered between the shoulders and at two different sites on the back by the owner on 23 MAR, 06 APR and 16 APR 2018 because of fleas seen on the animal. After product administration (unknown time to onset), the animal experienced scratching and slight irritation. At the time of this report, the animal was still scratching itself. The owner planned to go back to the vet in the next few days. This case is linked with the cases 18FR0550 and 18FR0551: similar non-serious AE in two other dogs from the same household after administration of FRONTLINE SPOT-ON CHIEN. Note: this case was considered as an adverse reaction and not as a SLOE since the presence of fleas was not reported. It was reported that the animal was under the following treatment: Vetmedin (unsubstantiated), Cardalis 2.5 and homeopathy. |
| 26-Apr-2018 | UAE; 18FR000573; -; France | **Species:** Canine **Breed:** Shetland Sheep Dog (Sheltie) **Sex:** M **Sex qualifier:** - **Age:** 5.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 14-Mar-2018 | 14-Mar-2018 | 0 Day(s) | D-C | FR-ANMV-18 CPVL 00382: Morning: Shetland Sheepdog dog applied with FRONTLINE SPOT ON CHIEN. In the afternoon: it displayed posterior ataxia, with hypersalivation. No vet examination. Duration of reaction: < or = 6 hours. Duration of reaction (precision): ongoing. Reason for treatment: fleas. Treatment of SAR: none. Investigations: ? Outcome of SAR: Unknown. FRONTLINE SPOT ON CHIEN () : 1 pipette; duration: once; onset time: < a few hours. |
| 23-Apr-2018 | UAE; 18FR000574; -; France | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.50 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** MILBEMAX Tablets (Elanco); **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 10-Apr-2016* | 12-Apr-2018* | 2 Day(s) | D-D | Suspected Adverse Event: As reported by the attending vet, Lully, a 2.5-year-old neutered male cat, 4 kg, in good condition, received 1 pipette of FRONTLINE COMBO SPOT ON CHAT (BN: 03661103006022, exp. date: JAN 2020) administered topically between the shoulders by the owner on 10 APR 2018. A few days after product administration, the animal experienced total loss of hairs (without any redness) at application site. No further information was available at the time of this report. Note: the animal also received Milbemax tablet (Elanco) (unknown dosage) on 10 APR 2018. It was reported that the animal had been regularly treated with FRONTLINE COMBO SPOT ON CHAT over the last 2 years without any adverse reactions. This case is linked with the case 18FR0575: similar non serious adverse reaction after administration of the same product to another cat from the same household. |
| 23-Apr-2018 | UAE; 18FR000575; -; France | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** MILBEMAX Tablets (Elanco); | 10-Apr-2016* | 12-Apr-2018* | 2 Day(s) | D-D | Suspected Adverse Event: As reported by the attending vet, Ghost, a 3-year-old neutered male cat, 4 kg, in good condition, received 1 pipette of FRONTLINE COMBO SPOT ON CHAT (BN: 03661103006022, exp. date: JAN 2020) administered topically between the shoulders by the owner on 10 APR 2018. A few days after product administration, the animal experienced total loss of hairs (without any redness) at application site. No further information was available at the time of this report. Note: the animal also received Milbemax tablet (Elanco) (unknown dosage) |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | | | | | on 10 APR 2018. It was reported that the animal had been regularly treated with FRONTLINE COMBO SPOT ON CHAT over the last 2 years without any adverse reactions. This case is linked with the case 18FR0574: similar non serious adverse reaction after administration of the same product to another cat from the same household. |
| 25-Apr-2018 | UAE; 18FR000576; -; France | **Species:** Canine **Breed:** Border Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Month(s) **Weight:** 11 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 19-Apr-2018 | 20-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the animal's owner, a male Border Terrier dog, born on 17 APR 2017, 11 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHIEN M (Batch: P60301AX, Exp. date: JAN 2019) administered between the shoulders by the owner on 19 APR 2018. 1 day after product administration, the animal experienced a first crust at application site, and then a second crust a little bit lower. The owner brought the animal to the vet who diagnosed an allergy to the product. The vet shaved the hairs at crust locations, desinfected and prescribed daily care with Bétadine on mornings and evenings in order to dry the skin, and if needed an antibiotic treatment would be prescribed. No further information was available at the time of this report. |
| 25-Apr-2018 | UAE; 18FR000591; -; France | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Apr-2018* | 01-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the animal's owner, a 4-year-old cat received FRONTLINE COMBO SPOT-ON CHAT (Batch: R40309FW, Exp. date: JAN 2020) administered by the owner on an unknown date (01 APR 2016 was chosen by default) for flea treatment. After product administration (unknown time to onset), the animal experienced total hair loss (as big as approximately a 2 euro coin) and then unusual reactions (ultra-rapid start, mad rush, irritation, stress, itching). No further information was available at the time of this report. This case is linked with the case 18FR0592: non-serious SLOE in the same animal after administration of the same product. |
| 25-Apr-2018 | UAE; 18FR000592; -; France | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Apr-2018* | 01-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the animal's owner, a 4-year-old cat received FRONTLINE COMBO SPOT-ON CHAT (Batch: R40309FW, Exp. date: JAN 2020) administered by the owner on an unknown date (01 APR 2016 was chosen by default) for flea treatment. After product administration (unknown time to onset) and according to the owner, the animal experienced a lack of efficacy because it was still scratching. No further information was available at the time of this report. This case is linked with the case 18FR0591: non-serious adverse reaction in the same animal after administration of the same product. |
| 03-May-2018 | UAE; 18FR000610; -; France | **Species:** Rabbit **Breed:** Rabbit (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 8.00 Week(s) **Weight:** 1 kg | 1 | 1 | 1 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the** | 30-Apr-2018 | 02-May-2018 | 2 Day(s) | D-A | FR-ANMV-18 CPVL 00674: D0: young rabbit applied by farmer with FRONTLINE SPRAY POMPE (size of bottle not specified) before being sold. D2 afternoon: presented by new owner with muscle tremor, prostration, anorexia. Despite therapy, it died during a convulsive episode, less than 3 hours after admission. Duration of reaction: < or = 12 hours. Duration of reaction (precision): <12 h. Reason for treatment: preventive ? Treatment of SAR: diazepam. Outcome of SAR: Unfavorable. FRONTLINE SPRAY POMPE () : "sprayed"; duration: Once; onset time: < 48 |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **product used ok?:** No (Species not indicated / recommended) | | | | | hours. |
| 28-Apr-2018 | UAE; 18FR000625; -; France | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 26-Mar-2018 | 27-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the animal's owner, Jack, a 8-year-old male Yorkshire dog, 3 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHIEN S (Batch and exp. date: unknown) administered topically between the shoulders by the owner twice at one month interval on 26 MAR and 27 APR 2018 in prevention. 1 hour after product administration, on 27 APR 2018, the animal experienced application site redness, warmth, and hair loss (of the great majority of the hairs). The owner applied Bépanthène at application site and the animal was in recovery at the time of this report. Note: the animal had already experienced redness of the skin at application site after the administration of the product on 26 MAR 2018. |
| 14-May-2018 | UAE; 18FR000635; -; France | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** - **Age:** 10.00 Year(s) **Weight:** 5-10 kg | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Apr-2018* | 01-Apr-2018* | 0 Day(s) | D-D | FR-ANMV-18 CPVL 00702: T0: 2 elderly cats (European and Norwegian Forest) cats administered with FRONTLINE COMBO SPOT-ON CHAT. T+1 hour: they both displayed application site alopecia (burned hair according to owner). A few days after: still application site alopecia, more visible on European cat (short-hair). Duration of reaction: < or = 14 days. Duration of reaction (precision): Ongoing (6-10 days). Reason for treatment: Preventive. Outcome of SAR: Unknown. FRONTLINE COMBO SPOT-ON CHAT () : 1 pipette/cat; duration: Once; onset time: 1 hour. |
| 15-May-2018 | UAE; 18FR000644; -; France | **Species:** Rabbit **Breed:** Rabbit (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 2.35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended) | 30-Mar-2018 | 31-Mar-2018 | 1 Day(s) | D-D | FR-ANMV-18 CPVL 00460: D0 evening: rabbit administered with FRONTLINE SPOT ON CHAT (on advice from pharmacist). D1 afternoon: it displayed diarrhoea and anorexia. Duration of reaction: < or = 6 hours. Duration of reaction (precision): Ongoing (a few hours). Reason for treatment: Preventive. Treatment of SAR: Shampoo. Investigations: None. Outcome of SAR: Unknown. FRONTLINE SPOT ON CHAT () : 1 pipette; duration: Once; onset time: 16 hours. |
| 16-May-2018 | UAE; 18FR000653; -; France | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** - **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the** | 01-May-2018* | 01-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the animal's owner, cats (unknown number (2 was chosen by default) and signalment), received FRONTLINE SPRAY (Batch and exp. date: unknown) administered by the owner on an unknown date (01 MAY 2018 was chosen by default). After product administration (unknown time to onset), the animals experienced hair loss, itching and crusts on the lower back requiring a visit to the vet (unspecified). No further information was available at the time of this report. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **product used ok?:** Unknown to Company | | | | | |
| 29-May-2018 | UAE; 18FR000695; -; France | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Not applicable **Age:** 6.00 Year(s) **Weight:** 3.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 26-Apr-2018 | 28-Apr-2018 | 2 Day(s) | D-C | FR-ANMV-18 CPVL 00680: Cat administered with FRONTLINE COMBO SPOT-ON CHAT. Within 2 days: it displayed anorexia and retching with dehydration. Treatment with fluid therapy and metoclopramide. Within 2 days: recovery. Duration of reaction: < or = 48 hours. Duration of reaction (precision): 2 days. Reason for treatment: Preventive. Treatment of SAR: Fluid therapy, metoclopramide. Investigations: None. Outcome of SAR: Favorable. FRONTLINE COMBO SPOT-ON CHAT () : 1 pipette; duration: Once; onset time: < 2 days. |
| 29-May-2018 | UAE; 18FR000696; -; France | **Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** - **Age:** 15.00 Year(s) **Weight:** 6.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 25-Apr-2018 | 26-Apr-2018 | 1 Day(s) | D-C | FR-ANMV-18 CPVL 00681: D0: European cat administered with FRONTLINE COMBO SPOT-ON CHAT. D1: it displayed trembling. Cat washed. D3: Recovery. Duration of reaction: < or = 48 hours. Duration of reaction (precision): 2 days. Reason for treatment: Preventive. Treatment of SAR: Shampoo. Investigations: None.Outcome of SAR: Favorable. FRONTLINE COMBO SPOT-ON CHAT () : 1 pipette; duration: Once; onset time: 1 day. |
| 28-May-2018 | UAE; 18FR000701; -; France | **Species:** Canine **Breed:** Shetland Sheep Dog (Sheltie) **Sex:** M **Sex qualifier:** Unknown **Age:** 13.00 Month(s) **Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 25-May-2018 | 25-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the animal's owner, Noë, a male Shetland Sheep dog, born on 30 APR 2017, 8 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHIEN S (Batch: R60503AX, Exp. date: FEB 2020) administered topically on the neck by the owner on 25 MAY 2018. Within 2 hours after product administration, on 25 MAY 2018, the animal began to run nervously around, turned its head in all directions, and tried to lick itself at application site. It had a very rapid breathing and was completly sluggish when its owner put it on her knees. The animal's behaviour had come back to normal at the time of this report. |
| 07-Jun-2018 | UAE; 18FR000737; -; France | **Species:** Rabbit **Breed:** Rabbit (unknown) **Sex:** M **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** 2.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | 29-Apr-2018 | 30-Apr-2018 | 1 Day(s) | D-D | FR-ANMV-18 CPVL 00662: T0: A young rabbit was administered with FRONTLINE COMBO SPOT-ON CHAT. T+26h: it displayed prostration, anorexia. Duration of reaction: < or = 6 hours. Duration of reaction (precision): Ongoing (A few hours). Reason for treatment: Preventive. Outcome of SAR: Unknown. FRONTLINE COMBO SPOT-ON CHAT () : 1 pipette; duration: Once; onset time: 26h. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** No (Species not indicated / recommended) | | | | | |
| 04-Jun-2018 | UAE; 18FR000750; -; France | **Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Neutered **Age:** 2.50 Year(s) **Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 21-May-2018 | 04-Jun-2018 | 2 Week(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Molly, a 2.5-year-old spayed female European cat, 3.5 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN and exp. date: unknown) administered topically by the owner in the neck on 21 MAY 2018 for flea treatment (one adult flea was seen in the animal's hairs). 2 weeks after product administration, on 04 JUN 2018, the owner observed flea eggs in the animal's hairs. No further information was available at the time of this report. |
| 06-Jun-2018 | UAE; 18FR000751; -; France | **Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** Unknown | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 21-May-2018 | 22-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the attending vet, Simba, a 6-year-old neutered male European cat, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: 40309FW, exp. date: JAN 2020) administered topically by the owner between the shoulders on 21 MAY 2018. 1 day after product administration, on 22 MAY 2018, the animal experienced hair loss at application site and a few days later on the base of tail. The skin was red. There was no scratching but it seemed that the animal pulled tufts of hairs (coded into Veddra as "Localised itching"). No further information was available at the time of this report. Note: the owner reported that the animal had already experienced hair loss between the shoulders last year after administration of FRONTLINE COMBO SPOT-ON CHAT or FRONTLINE SPOT-ON CHAT. |
| 07-Jun-2018 | UAE; 18FR000752; -; France | **Species:** Feline **Breed:** - **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 28-May-2018 | 28-May-2018 | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Bagherra, a spayed female Cat, 5 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT(Batch: R41004DW, Exp. date: AUG 2020) administered topically by the owner between the shoulders on 28 MAY 2018. After product administration, on 28 MAY 2018, the animal experienced a lack of efficacy with fleas still visible on the animal. The SLOE was still ongoing at the time of this report. Note: the exact animal's age was unknown but it was reported that it had been adopted ten years ago. The animal was treated every two months with a dewormer (last date of administration unknown). |
| 06-Jun-2018 | UAE; 18FR000753; -; France | **Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 4 - 4.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / | 27-May-2018 | 01-Jun-2018 | 5 Day(s) | D-D | Suspected Adverse Event: As reported by the animal's owner, Simba, a 6-year-old neutered male cat, between 4 and 4.5 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (Batch: R41004DW, Exp. date: AUG 2020) administered topically on the neck by the owner on 27 MAY 2018. 5 days after product administration, on 01 JUN 2018, the animal experienced hair loss on the neck and seemed a little sluggish. Hair loss was still ongoing at the time of this report. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | |
| 04-Jun-2018 | UAE; 18FR000754; -; France | **Species:** Canine<br>**Breed:** Lhasa Apso<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 28-May-2018 | 28-May-2018 | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Eliah, a 8-year-old spayed female Lhassa Apso dog, 5 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHIEN S (Batch: R60103AX, Exp. date: DEC 2019) administered topically by the owner between the shoulders on 28 MAY 2018. After product administration (unknown time to onset), on 28 MAY 2018, the animal experienced a lack of efficacy with fleas still visible on the animal. No further information was available at the time of this report. |
| 28-May-2018 | UAE; 18FR000755; -; France | **Species:** Canine<br>**Breed:** Border Collie<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.50 Year(s)<br>**Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 05-May-2018 | 05-May-2018 | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, a 3.5-year-old male Border Collie dog, 7 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHIEN M (BN and exp. date: unknown) administered topically by the owner between the shoulders on 05 MAY 2018. After product administration (unknown time to onset), on 05 MAY 2018 after a walk in the woods, ticks were seen on the animal. The animal recovered on an unknown date. Note: the animal was usually treated with FRONTLINE TRI-ACT, but not this time because the product was not available at the time of the administration. |
| 06-Jun-2018 | UAE; 18FR000772; -; France | **Species:** Feline<br>**Breed:** European<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 3 - 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Mar-2018 | 03-Jun-2018 | 2 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Jojo, a 4-year-old neutered male European cat, 3 to 4 kg, in good condition, received 1 pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: P41103AW and exp. date: SEP 2019) administered topically by the owner between the shoulders every 4 weeks between 01 MAR and 01 JUN 2018. 2 days after the last product administration, the animal was still covered by fleas. On 12 JUN 2018, the animal had recovered. Note: it was reported that the owner had been using the product for some years for her cat (no more information). |
| 11-Jun-2018 | UAE; 18FR000776; -; France | **Species:** Feline<br>**Breed:** European<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 16.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous | 09-May-2018 | 09-Jun-2018* | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Gribouille, a 16-year-old neutered male European cat, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (Batch: R21318AX, Exp. date: JUL 2020) administered topically by the owner between the shoulders on 09 JUN 2018 for flea treatment. After product administration (unknown time to onset), the animal experienced a lack of efficacy with fleas still visible on the animal. No further information was available at the |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **Was the product used ok?:** Unknown to Company | | | | | time of this report. Note: the animal had been treated with FRONTLINE SPOT-ON CHAT on 09 MAY 2018 with a good efficacy, however the owner had at that time also treated the animal's environment with FRONTLINE Spray Habitat. This case is linked with the case 18FR0777: non serious SLOE in another cat from the same household after administration of the same product (same batch number). |
| 11-Jun-2018 | UAE; 18FR000777; -; France | **Species:** Feline **Breed:** Turkish Angora **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 09-May-2018 | 09-Jun-2018* | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Praline, a 4-year-old spayed female Angora cat, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (Batch: R21318AX, Exp. date: JUL 2020) administered topically by the owner between the shoulders on 09 JUN 2018 for flea treatment. After product administration (unknown time to onset), the animal experienced a lack of efficacy with fleas still visible on the animal. No further information was available at the time of this report. Note: the animal had been treated with FRONTLINE SPOT-ON CHAT on 09 MAY 2018 with a good efficacy, however the owner had at that time also treated the animal's environment with FRONTLINE Spray Habitat. This case is linked with the case 18FR0776: non serious SLOE in another cat from the same household after administration of the same product (same batch number). |
| 07-Jun-2018 | UAE; 18FR000778; -; France | **Species:** Feline **Breed:** European **Sex:** X **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 3 - 4 kg | 5 | 5 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 01-May-2018* | 01-Jun-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy: As reported by the animal's owner, 5 cats from the same household (Gavroche, Gabin, Blanchette, Chanel, and Ying Yang: 2 neutered males and 3 spayed females, aged between 6 and 7 years for 2 cats and between 2 and 3 years for 3 cats, weighing between 3 and 4 kg) in good condition received one pipette of FRONTLINE COMBO SPOT-ON CHAT (Batch and exp. date: unknown) administered topically by the owner between the shoulders on 01 JUN 2018 for flea treatment. After product administration (unknown time to onset), the animals still had fleas and scratched themselves a lot. The SLOE was ongoing at the time of this report. Note: it was reported that the animals had been treated with FRONTLINE COMBO SPOT ON CHAT every 4 weeks (dates of administration not specified). This case is linked with the case 18FR0779: SLOE in a dog from the same household after administration of FRONTLINE COMBO CHIEN. |
| 07-Jun-2018 | UAE; 18FR000779; -; France | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 3.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 01-May-2018* | 01-Jun-2018* | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Nikita, a spayed female crossbred dog, aged between 2 and 3 years, 3.5 kg, in good condition received one pipette of FRONTLINE COMBO SPOT-ON CHIEN (unsubstantiated product) (Batch and exp. date: unknown) administered topically by the owner between the shoulders on 01 JUN 2018 for flea treatment. After product administration (unknown time to onset), the animal still had fleas and scratched itself a lot. The SLOE was ongoing at the time of this report. Note: it was reported that the animal had been treated with FRONTLINE COMBO SPOT ON CHIEN every 4 weeks (dates of administration not specified). This case is linked with the case 18FR0778: SLOE in 5 cats from the same household after administration of FRONTLINE COMBO CHAT. |
| 07-Jun-2018 | UAE; 18FR000787; -; France | **Species:** Feline **Breed:** Feline (unknown) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 31-May-2018 | 01-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the attending vet, Simba, a 8-year-old neutered male cat, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** Unknown | | | | METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | R40309FW , exp. date: 31 JAN 2020) administered topically by the owner on the interscapular area on 31 MAY 2018. 1 day after product administration, on 01 JUN 2018, the animal experienced application site hair loss. Then hair loss extended to the neck and a new hair loss area appeared at the base of the tail. On 06 JUN 2018, as the animal's health condition was not improving, the animal was brought to the vet who injected 5 ml of DEPO-MEDROL. On 07 JUN 2018, no improvement was observed, very severe erythema appeared on the neck, and the animal had lost weight. On 08 JUN 2018, the animal was washed and erythema clearly improved. No further information was available at the time of this report. Note: it was reported that the animal had already been treated with the product (unknown date) and had reacted (unspecified reaction). UPDATE 23 JUL 2018: Suspected Adverse Event: As reported by the attending vet, Simba, a 8-year-old neutered male cat, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: R40309FW , exp. date: 31 JAN 2020) administered topically by the owner on the interscapular area on 31 MAY 2018. 1 day after product administration, on 01 JUN 2018, the animal experienced application site hair loss. Then hair loss extended to the neck and a new hair loss area appeared at the base of the tail. On 06 JUN 2018, as the animal's health condition was not improving, the animal was brought to the vet who injected 5 ml of DEPO-MEDROL. On 07 JUN 2018, no improvement was observed, very severe erythema appeared on the neck, and the animal had lost weight. On 08 JUN 2018, the animal was washed and erythema clearly improved. No further information was available at the time of this report. Note: it was reported that the animal had already been treated with the product (unknown |
| 13-Jun-2018 | UAE; 18FR000790; -; France | **Species:** Canine<br>**Breed:** Retriever (Labrador, Black)<br>**Sex:** U<br>**Sex qualifier:** -<br>**Age:** 9.00 Year(s)<br>**Weight:** 33 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 09-Jun-2018 | 09-Jun-2018 | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, a Labrador Retriever dog, born on 27 JAN 2009, 33 kg, ID 2GEK383, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHIEN L (Batch: R21427AX, Exp. date: AUG 2020) administered topically by the owner on 09 JUN 2018. After product administration (unknown time to onset), alive fleas were still visible on the animal (and no dead fleas were seen). A second and a third pipette were administered on 11 and 13 JUN 2018, respectiveley, but without any efficacy. No further information was available at the time of this report. |
| 14-Jun-2018 | UAE; 18FR000791; -; France | **Species:** Feline<br>**Breed:** European<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 6 - 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** MORPHINE;<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 09-May-2018 | 09-May-2018 | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Beijo, a 10-year-old neutered male European cat, 6-7 kg, ID xx150, in poor condition (the animal was under morphine because of a painful limb) received one pipette of FRONTLINE COMBO SPOT-ON CHAT (Batch: R40505DW, Exp. date: unknown) administered topically by the owner on 09 MAY 2018 for flea treatment. After product administration (unknown time to onset), fleas were still visible on the animal. A second and a third pipette were administered on the animal on 27 MAY and 10 JUN 2018, respectively, but without any efficacy. No further information was available at the time of this report. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Unknown to Company | | | | | |
| 15-Jun-2018 | UAE; 18FR000792; -; France | **Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose) | 09-Jun-2018 | 10-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the animal's owner, a 1-year-old male European cat, 3 kg, in good condition, received two pipettes of FRONTLINE COMBO SPOT-ON CHAT (Batch: unknown , Exp. date: APR 2020) administered between the shoulders by the owner on 09 JUN 2018. 1 day after product administration, the animal experienced hair loss, then skin irritation until bleeding, crust of about 5-6 cm. No further information was available at the time of this report. Note: "Skin bleeding" was coded into Veddra by "Skin sore". |
| 16-Jun-2018 | UAE; 18FR000814; -; France | **Species:** Canine **Breed:** Cane Corso **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 50 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Others) | 08-Jun-2018 | 10-Jun-2018 | 2 Day(s) | D-B | Suspected Adverse Event: As reported by the animal's owner, a 2-year-old female Cane Corso dog, 50 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHIEN XL (BN and exp. date: unknown) administered topically by the owner between the shoulders and at the base of the tail on 08 JUN 2018. 2 days after product administration, on 10 JUN 2018 in the morning, the animal experienced a first epileptic seizure followed by three others (unspecified dates). It was brought to the clinic on 11 JUN 2018 in the morning where it had a new crisis. The vet performed a blood sample (normal results), injected valium and referred the animal to another clinic in order to perform a CT scan that was normal. The animal was kept at the clinic under monitoring and underwent a lumbar puncture (no abnormalities). Phenoleptil (0.5 tablet of 100 mg and 50 mg in the mornings and evenings) was prescribed for one month. After this episode, the animal recovered two days after treatment start with Phenoleptil. At the time of this report, the event was reported as ongoing. Off-label use: the product was administered at two different sites instead of one as recommended in the SPCs.<br><br>No further information was available at the time of this report. |
| 09-Jun-2018 | UAE; 18FR000815; -; France | **Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 1.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 14-May-2018 | 14-May-2018 | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Muty, a 1-year-old European male cat, 1.5 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (Batch: R40203FW, Exp. date: JAN 2020) administered topically by the owner between the shoulders on 14 MAY 2018. Immediately after product administration, the animal experienced a lack of efficacy with fleas still visible on the animal and the environment was infested. Another pipette of FRONTLINE COMBO SPOT-ON CHAT (Batch: R40203FW, Exp. date: JAN 2020) was administered on 08 JUN 2018 but without any effect. The animal was brought to a vet (unknown) who prescribed a tablet (unspecified product) and it recovered. |
| 18-Jun-2018 | UAE; 18FR000816; -; France | **Species:** Feline **Breed:** European **Sex:** M | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 15-May-2018 | 15-May-2018* | N/A | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Pistache, a 5-year-old neutered male European cat, 4 kg, in good condition, received pipettes of FRONTLINE COMBO SPOT-ON |

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| | | **Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 4 kg | | | | METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | CHAT (Batch: R20701AX, Exp. date: APR 2020) administered topically by the owner between the shoulders from 15 MAY to 07 JUN 2018 for flea treatment (unknown number of pipettes administered and rhythm of administration). After product administration (unknown time to onset, the animal experienced a lack of efficacy with fleas still visible on the animal and in the owner's flat. No further information was available at the time of this report. Note: the owners reported that she had also treated the cat's environment (flat) with 3 foggers (unspecified). |
| 17-Jun-2018 | UAE; 18FR000817; -; France | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** -<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S<br>METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jun-2018* | 01-Jun-2018* | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, a cat (unknown signalment and health condition prior to product administration), received FRONTLINE COMBO SPOT-ON CHAT (BN and exp. date: unknown) on an unknown date (01 JUN 2018 was chosen by default). After product administration (unknown time to onset), fleas were still visible on the animal. No further information was available at the time of this report. |
| 19-Jun-2018 | UAE; 18FR000818; -; France | **Species:** Feline<br>**Breed:** European<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 16.00 Year(s)<br>**Weight:** 4 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S<br>METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 25-May-2018 | 25-May-2018 | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Picasso, a 16-year-old neutered male European cat, about 4 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (Batch: R21318AX, Exp. date: JUL 2020) administered topically by the owner between the shoulders on 25 MAY 2018 for flea treatment. Immediately after product administration, fleas were still visible on the animal. Two other pipettes of FRONTLINE COMBO SPOT-ON CHAT (Batch: R21318AX, Exp. date: JUL 2020) were administered at about one week interval with a last administration on 15 JUN 2018, without any effect . No further information was available at the time of this report. |
| 20-Jun-2018 | UAE; 18FR000849; -; France | **Species:** Feline<br>**Breed:** European<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S<br>METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Apr-2018* | 15-Apr-2018* | 2 Week(s) | D-D | Suspected Adverse Reaction and Lack of Efficacy: As reported by the animal's owner, a entire male European cat, in good condition, received FRONTLINE COMBO SPOT-ON CHAT (BN and exp. date: unknown) administered topically on the neck by the owner at the beginning of APR 2018 for flea and tick treatment. Less than 2 weeks after product administration, two alive ticks were found on the animal that experienced two patches (no further details were provided) in the neck. The owner applied Biseptine on the patches and the animal recovered. Note: it was reported that the owner has two cats living both indoors and outdoors, but that the other cat did not receive the product. |
| 17-Jun-2018 | UAE; 18FR000850; -; France | **Species:** Feline<br>**Breed:** Feline (unknown) | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT | 01-Jun-2018* | 01-Jun-2018* | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Eros, a neutered male cat, in good condition, received FRONTLINE SPOT-ON CHAT (BN and exp. date: unknown) |

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| | | **Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** - | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** - | | | | | administered topically by the owner on the neck at the beginning of JUN 2018. After product administration (unknown time to onset), the owner did not see any efficacy on the fleas. No further information was available at the time of this report. |
| 21-Jun-2018 | UAE; 18FR000852; -; France | **Species:** Feline<br>**Breed:** Birman<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 19-Jun-2018 | 19-Jun-2018* | N/A | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Snow, a Birman cat received FRONTLINE SPRAY (Batch : R01507A, Exp. date: unknown) administered topically by the owner on 19 and 20 JUN 2018 (no more details were provided and it is unknown if the product was administered twice or if product administration started late in the evening on 19 JUN 2018) for flea treatment. After product administration (unknown time to onset), fleas were still visible on the animal. The SLOE was still ongoing at the time of this report. |
| 22-Jun-2018 | UAE; 18FR000853; -; France | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** U<br>**Sex qualifier:** -<br>**Age:** 12.00 Year(s)<br>**Weight:** 21 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 21-Jun-2018 | 21-Jun-2018 | 0 Day(s) | D-C | Suspected Adverse Event: As reported by the animal's owner, Boheme, a 12-year-old Yorkshire Terrier dog, 2.1 kg, received FRONTLINE COMBO SPOT-ON CHIEN (product unsubstantiated) (BN and exp. date: unknown) administered topically between the shoulders by the owner on 21 JUN 2018. On 21 JUN 2018 in the evening, the animal experienced vision impairment of the right eye. The owner suspected that the animal scratched itself with its paw in the eye and that the product may have penetrated into the eye. The animal had trembled all night. No further information was available at the time of this report. |
| 21-Jun-2018 | UAE; 18FR000854; -; France | **Species:** Canine<br>**Breed:** Terrier (Jack Russell)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 10.35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 11-Feb-2018 | 11-Feb-2018 | 0 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, Jaguar, a male Jack Russel Terrier dog, born on 11 JUN 2014, 10.35 kg, received FRONTLINE SPOT-ON CHIEN (product unsubstantiated) (BN and exp. date: unknown) administered by the owner on 11 FEB 2018 for flea treatment. After product administration, fleas were still present. No further information was available at the time of this report. This case is linked with the case 18FR000041: non serious SLOE in the same dog and with the same product on 04 JAN 2018. |
| 26-Jun-2018 | UAE; 18FR000868; -; France | **Species:** Canine<br>**Breed:** Setter (English)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 7.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 11-Jun-2018 | 26-Jun-2018 | 15 Day(s) | D-E | Suspected Lack of Efficacy: As reported by the animal's owner, a 7 year-old Female Setter crossbred Spaniel dog received one pipette of FRONTLINE SPOT-ON CHIEN L (BN and exp. date: unknown) administered topically by the owner on an unknown date (01 JUN 2018 was chosen by default) for flea treatment. 15 days after product administration, the animal experienced a lack of efficacy. The number of fleas present on the animal decreased a little but a lot of fleas were still visible. No further information was available at the time of this report. |

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| | | | | | | **ok?:** Unknown to Company | | | | | |
| 28-Jun-2018 | UAE; 18FR000878; -; France | **Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** - **Age:** 2.00 Month(s) **Weight:** 1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 02-Jun-2018 | 03-Jun-2018 | 1 Day(s) | D-C | FR-ANMV-18 ANMV 01283: A 2-month old cat received for the 1st time 1 pipette of FRONTLINE SPOT ON CHAT on 02-JUN-2018. The following day, the kitten presented with ataxia and generalised tremor. Vigilance was kept. The kitten had been washed twice with washing-up liquid, received fluids and lipidic solution (2 ml/kg then 15 ml/hour for 1 hour twice). The event lasted 2 days. Outcome unknown. Duration of reaction: Duration of reaction (precision): 2 Day. Reason for treatment: Preventive. |
| 17-Apr-2018 | UAE; 18HU000002; -; Hungary | **Species:** Feline **Breed:** Siamese **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 12-Mar-2018 | 12-Mar-2018* | 0 Day(s) | D-D | Suspected Lack of Efficacy: as reported by the owner, a cat, Siamese, male neutered, 6 years old, 5 kg, in good health condition, was treated with FRONTLINE 50mg/0,5ml FOR CATS (BN, exp date unknown) 1 dose administered by the owner on 12 Mar 2018. The product was given for treatment against fleas (flea infestation and scratching before the FRONTLINE application). The date of onset is unknown. Scratching and disquiet remained after treatment. Pruritus and nervous attitude were reported.The owner checked his cat for fleas and he seemed to be still infested with live fleas despite the FRONTLINE application. On 18 Mar 2018, a treatment with FRONTLINE COMBO was started and the reaction stopped. This is the extent of information available. The animal was previously exposed to FRONTLINE SPOT ON and another drugs for parasite control. No more informations are available concerning potential previous reactions. |
| 23-Apr-2018 | UAE; 18IE000018; County Carlow; Ireland | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 6 | 6 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON; FIPRONIL SPOT ON CAT; **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-Apr-2018* | N/A | D-D | As reported by the animal owner, a male feline of unknown age, breed, reproductive status and weight, and in very bad condition, was administered FRONTLINE SPRAY (batch and expiry unknown) via an unknown route, to an unknown site by the attending vet at an unknown dose on an unknown date as the animal was covered in lice. The animal owner reports that they found the stray cat and placed him in their garage as they have 5 other cats and so did not want to risk bringing the animal into the home in case he had anything contagious. The animal owner made the animal comfortable in the garage and fed and checked him regularly. As soon as the vets reopened the owner had him checked over and they said that he was covered in lice. The treated him immediately (head to toe) with FRONTLINE SPRAY and a FRONTLINE SPOT ON (batch and expiry unknown) when going home. As advised, the animal owner disposed of any bedding that he had used and washed any new bedding every couple of days. After a week or so, when the animal owner thought that the lice/fleas would have been well gone, they brought the animal into their home and he mixed with the other cats, who they noticed then started scratching a lot. All the animals got treated again with FRONTLINE COMBO SPOT ON CATS (batch and expiry unknown), including the new cat again. The animal owner also changed the bedding and treated the house, the garage, their car with Acclaim as advised by the attending vet. After just over three weeks, all the cats were again treated with FRONTLINE COMBO SPOT ON CATS, but they are scratching more than ever and the animal owner is still getting bitten. Their cats seem very |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | uncomfortable, scratching and grooming constantly and even the attending vet has said this should not be the case. The animal owner reports that they are not at all impressed with the product, and think that they may need to try something else. The animal owner reports that they seem to have an allergic reaction to the bites and had to |
| 07-Jun-2018 | UAE; 18IE000020; Co. Louth; Ireland | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 1.85 kg | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Aug-2015 | 12-May-2018 | 0 Day(s) | D-D | As reported by the manager at the practice, Ramble,a female neutered Domestic Shorthaired feline, born 21 JUL 2012, weighing 1.85 kg and in fair condition, and two other felines, were administered FRONTLNE COMBO SPOT ON CAT (batch P41506CW, expiry NOV 2019) topically by the animal owner at a dose of 1 dosage form on 12 MAY 2018 as a preventative treatment. The manager at the practice reports that the client phoned to report excess salivation, agitation, increased drinking, stress and frothing from the mouth approximately 10 to 15 minutes post application. This went on for approximately 3 to 4 hours post application until it calmed down. It is reported that the animal is all back to normal and the animal owner is not worried now. The animal owner reported to the manager that they could not rule out that the animal didn't lick either itself or the other household animals. The animal was not seen by the attending vet, advice was given to monitor and maybe use a different type of product next time round. |
| 14-Jun-2018 | UAE; 18IL000008; -; Israel | **Species:** Feline **Breed:** Maine Coon Cat **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** 6 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jun-2018* | 14-Jun-2018* | 13 Day(s) | D-E | Suspected Lack of Efficacy Report: as reported by owner, a female Maine Coon cat, aged 8 months, weighing less than 6, (other signalments unknown) received FRONTLINE PLUS CAT (BN, exp date unknown) 1 dose, by topical route on an unknown date (01 June 2018 was chosen by default). Two weeks after product administration (14 June 2018 was chosen by default), fleas are seen on the cat. It is reported as normal, as the cat is in house and environment is not treated. The product was used as per label instructions. The animal is reported alive with sequelae. The vet reported another similar case form the same household (see case 18IL000010). This is the extent of information available. |
| 14-Jun-2018 | UAE; 18IL000010; -; Israel | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** 6 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jun-2018* | 14-Jun-2018* | 13 Day(s) | D-E | Suspected Lack of Efficacy Report: as reported by owner, a female mixed cat, aged 7 years, weighing less than 6 kilograms (other signalments unknown) received FRONTLINE PLUS CAT (BN, exp date unknown), 1 dose, by topical route, on an unknown date (01 June 2018 chosen by default). Two weeks after product administration (14 June 2018 chosen by default), fleas are seen on the cat. It is reported as normal, for the cat is in house and environment is not treated. The product was used as per label instructions. The animal is reported alive with sequelae. The vet reported another similar case form the same household (see case 18IL000008). This is the extent of information available. |
| 23-May-2018 | UAE; 18IT000072; -; Italy | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** F **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products | 04-May-2018 | 14-May-2018 | 10 Day(s) | D-E | Suspected lack of efficacy: the animal owner reported that on 04 May 2018 he administered FRONTLINE SPOT-ON DOGS S (BN P21507BX, exp. date 10/2019) topically to a small crossbred female dog (approximately 2 year old, approximately 5 kg) and that after 10 days the dog had ticks. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 5 kg* | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | |
| 05-Jun-2018 | UAE; 18IT000078; -; Italy | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2015* | 01-Jun-2018* | 0 Day(s) | D-E | Suspected Lack Of Efficacy: As reported by the owner, 2 dogs (age, weight, breed unknown) received FRONTLINE COMBO DOG (1 pipette per animal, BN, exp date unknown, product unsubstantiated) administered by the owner for years on unknown dates once a month (unknown start date: 01 Jan 2015 chosen by default; unknown end date: 01 Jun 2018 chosen by default). The owner declares to wash the animals and after 24 hours to apply the product on clean skin. However, the dogs are still infested with fleas. Note: also two cats live in the same household and are never let outdoor, except for a balcony. The cats were treated with FRONTLINE COMBO CAT ( LOE reported see case n. 18IT000079). Follow-up information received on 10 Jul 2018: product BN R60113BX, exp date 12/2019. |
| 05-Jun-2018 | UAE; 18IT000079; -; Italy | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2015* | 01-Jun-2018* | 0 Day(s) | D-E | Suspected Lack Of Efficacy: As reported by the owner, 2 cats (age, weight, breed unknown) received FRONTLINE COMBO CAT (1 pipette per animal, BN, exp date unknown) administered by the owner for years on unknown dates once a month (unknown start date: 01 Jan 2015 chosen by default; unknown end date: 01 Jun 2018 chosen by default). The owner declares to wash the animals and after 24 hours to apply the product on clean skin. However, the cats are still infested with fleas. Note: also two dogs live in the same household and are never let outdoor, except for a balcony . The dogs were treated with FRONTLINE COMBO DOG ( LOE reported see case n. 18IT000078). |
| 15-Jun-2018 | UAE; 18IT000087; -; Italy | **Species:** Feline<br>**Breed:** Feline mixed/various breeds<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 15.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-May-2018 | 01-Jun-2018* | N/A | D-E | Suspected Lack of Efficacy: as reported by the animal owner, 2 cats (one male, neutered, 6 year old crossbred and one female, 15 year old crossbred) received FRONTLINE COMBO SPOT ON CATS (BN R40807AW, expiry date Jul 2020, unknown dosage) administered topically by the animal owner on 01 May 2018 and again on 11 Jun 2018. They have been infested with fleas since beginning of June 2018 (01 Jun 2018 chosen by default). The 2 cats live indoor and are the only companion animals in the house. They are treated with antiparasitics only during summer season. In the past years they received FRONTLINE SPOT ON CATS, but this year they received FRONTLINE COMBO SPOT ON CATS. |
| 03-May-2018 | UAE; 18IT000114; -; Italy | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 10.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | 19-Apr-2018* | 03-May-2018 | 0 Day(s) | D-D | Suspect Adverse Reaction: as reported by the animal owner, a cat (female, 10 year old, unknown weight, infested with fleas) received FRONTLINE COMBO CATS (unknown BN, exp date, topically/cutaneous) on 03 May 2018 administered by the owner. The product was administered 2 weeks after previous product application as the fleas had reappeared ( Suspect Lack of Efficacy). The cat licked it off and started drooling and jumping around . |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | Cutaneous<br>**Was the product used ok?:** No (Overdose) | | | | | |
| 23-May-2018 | UAE; 18JP000194; Shizuoka; Japan | **Species:** Canine<br>**Breed:** -<br>**Sex:** U<br>**Sex qualifier:** -<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 1 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** other<br>**Was the product used ok?:** Unknown to Company | 13-Mar-2018* | 13-Mar-2018 | N/A | D-A | As reported by the attending veterinarian, Frontline Spray (Lot number: R02804A, Expiry date: Jun 2019, Date of administration: unknown, external, 1 spray pump or more) was administered to the puppy (Kai dog, BW, age and gender: unknown) by the owner, who is a breeder of a Kai dog. On 23 May 2018, the owner called the animal hospital to report that the puppy died on 23 May 2018. The owner explained that the puppy died with foaming at the mouth this morning after administration of frontline spray. The veterinarian (Assistant director of the animal hospital) asked the owner about the dose etc. and the owner mentioned that the dosage might have been excessive and said that the owner preferred Myfleaguard which the amount of the dose was easier to see. The veterinarian asked the owner to bring the dead puppy and the other puppies that were administered, but the owner got upset for being suspected. There has been no visit to the hospital as of 24 May 2018. Back in 06 Mar 2018, the owner visited the animal hospital without the animal asking for flea prevention. Frontline Spray was ordered to be picked up at a later date. On 13 Mar 2018, the owner visited the hospital and Frontline Spray was prescribed and hair coat conditioner for dog/cat "Humilac" was also purchased. At that time, the owner was instructed that the application should be one spray pump per head at home. Based on the report 18JP000195 (internal reference # FLS18-001), another puppy owned by the same owner experienced similar symptoms and died on May 21, 2018 after Frontline Spray administration (detail unknown). |
| 23-May-2018 | UAE; 18JP000195; Shizuoka; Japan | **Species:** Canine<br>**Breed:** -<br>**Sex:** U<br>**Sex qualifier:** -<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 1 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** other<br>**Was the product used ok?:** Unknown to Company | 13-Mar-2018* | 13-Mar-2018 | N/A | D-A | As reported by the attending veterinarian, Frontline Spray (Lot number: R02804A, Expiry date: Jun 2019, Date of administration: unknown, external, 1 spray pump or more) was administered to the puppy (Kai dog, BW, age and gender: unknown) by the owner, who is a breeder of a Kai dog. On 23 May 2018, the owner called the animal hospital to report that the puppy died on 21 May 2018. The owner explained that the puppy died with foaming at the mouth this morning after administration of frontline spray. The veterinarian (Dr. Takahiro Oba, Assistant director of the animal hospital) asked the owner about the dose etc. and the owner mentioned that the dosage might have been excessive and said that the owner preferred Myfleaguard which the amount of the dose was easier to see. The veterinarian asked the owner to bring the dead puppy and the other puppies that were administered, but the owner got upset for being suspected. There has been no visit to the hospital as of 24 May 2018. Back in 06 Mar 2018, the owner visited the animal hospital without the animal asking for flea prevention. Frontline Spray was ordered to be picked up at a later date. On 13 Mar 2018, the owner visited the hospital and Frontline Spray was prescribed and hair coat conditioner for dog/cat "Humilac" was also purchased. At that time, the owner was instructed that the application should be one spray pump per head at home. Based on the report 18JP000194 (internal reference # FLS18-002), another puppy owned by the same owner experienced similar symptoms and died on May 23, 2018 after Frontline Spray administration (detail unknown). |

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| 03-Jun-2018 | UAE; 18JP000261; Tokyo; Japan | **Species:** Canine **Breed:** Mixed Breeds / various **Sex:** F **Sex qualifier:** - **Age:** 9.00 Year(s) **Weight:** 4.9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** steroid; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 02-Jun-2018 | 02-Jun-2018 | N/A | D-C | As reported by the attending veterinarian, on 02 Jun 2018, at 10:30 AM, a 9 years old female spayed mix (Chihuahua and papillon) dog was brought to the animal hospital and received Frontline Plus Dog XS (Lot number: unknown, Expiry date: unknown, topical, 0.5 mL) by the veterinarian. The dog received Frontline Plus Dog for the first time and was in good health then. At the time of administration, care was taken to keep the dog in a well-ventilated environment. On the same day, at 11:30 AM, the owner called the hospital to report that the dog vomited foam three times after returning home. According to the owner, the dog did not seem to have licked the drug. On the same day, at 3:04 PM, the dog was brought back to the hospital. The body temperature was 38.8 degrees Celsius. Cerenia 0.5 mL and prednisolone 0.5 mL were subcutaneously administered. Subsequently, the dog recovered. When the dog receives drugs including vaccine, a steroid is usually administered in combination, since the dog is allergic to cephem antibiotic and vaccine. |
| 31-May-2018 | UAE; 18KR000029; -; South Korea | **Species:** Canine **Breed:** Canine Other **Sex:** F **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 10.1 kg | 1 | 1 | 0 | **Product used:** Frontline (Non-specific) **Other products used:** FIPRONIL 8.3% / S-METHOPRENE 10% / PRAZIQUANTEL 8.3% / EPRINOMECTIN 0.4% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 25-May-2018 | 26-Apr-2018 | N/A | D-D | As reported by attending vet, the canine (Jindo dog, 7 Months, Female, 10.1kg) was administrate with Frontline (Batch number: R62201AL, Exp. Date : Sep 2020) by attending vet on 25 May 2018. Broadline was used before one month in this patient. That time, the dog had some redness. Within one day, hair loss and redness, inflammation (skin, severe) occurred after administrating of Frontline . The dog is receiving the treatment of disinfection dressing and ointment in the hospital (Outpatient). |
| 11-Apr-2018 | UAE; 18MX000010; -; Mexico | **Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** X **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 12 - 13 kg | 10 | 3 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | 01-Apr-2018 | 10-Apr-2018 | 9 Day(s) | D-D | As reported by the animal owner, 10 dogs (breed: Cocker Spaniel, female and male group, age: between 1 and 4 years, weight: 12-13 kg, status prior/at time of vaccination: reported to be good) were treated against flea and ticks with Frontline Spray, on (batch: R01902A; expiration date: April 2019, storage conditions: unknown) April 1, 2018, (route of administration: cutaneous, reason of use: deworming, dose: 4 aspersions = off label: misuse type: dose not recommended/indicated ). The application of the product was made in all the herd dividing the animals in 4 parts (cranial, dorsal and caudal). On April 10, it was noticed that 3 animals showed a located, superficial and wet lesion in the head with presence of erythema, alopecia and pruritus . It is the first time that this product is used, previously, it was used the Front line Top Spot for the deworming. No further information is expected. |
| 13-Apr-2018 | UAE; 18NL000057; -; Netherlands | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products** | 31-Mar-2018* | 07-Apr-2018* | 1 Week(s) | D-D | Suspected Adverse Event: As reported by the pet owner the cat Bengel (Domestic Shorthair, a neutered male, born 01042012, 3.9 kg) received FRONTLINE COMBO KAT (Batch nr and expiry date unknown) administered by the owner topically between the shoulders end of March 2018. Approximately a week later the cat experienced small crust on the back and a hotspot near the |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 3.9 kg | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | application site and ventral of the right ear. Itching was noticed since a few days. On 1104218 the cat was examined by the veterinarian; Cavasan eye ointment was prescribed for the hotspot near the eye and the cat received Bravecto. The cat has been treated regularly (approximate every 6 weeks) with Frontline for several years and has never shown side-effects. There has been no change in diet. The cat has outdoor access. |
| 13-Apr-2018 | UAE;<br>18NL000059;<br>-; Netherlands | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 21-Oct-2017* | 12-Apr-2018 | 6 Day(s) | D-D | As reported by the owner, the cat (Domestic Shorthair Crossbred, female, age unknown, 2 kg) received FRONTLINE COMBO KAT (Batch no and expiry date unknown), topically in the neck, administered by the owner in October 2017, early in March and April 2018. The cat entered the household in October 2017 after she was found in the neighborhood. The cat has had several health issues and receives medication against hyperthyroidism. Because the cat was scratching a lot the cat was examined by the veterinarian on 12042018: two fleas were detected on the cat. The cat has no outdoor access. The owner expects lack of efficacy. |
| 18-Apr-2018 | UAE;<br>18NL000060;<br>-; Netherlands | **Species:** Feline<br>**Breed:** Norwegian Forest Cat<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 9.50 Year(s)<br>**Weight:** 5 kg | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 07-Nov-2017* | 10-Dec-2017* | 3 Day(s) | D-A | Suspected Adverse Event: As reported by the owner the cat Pasha (Norway Forest cat x Maine Coon, neutered male, 9.5 years, approximately 5 kg) received FRONTLINE COMBO KAT (batch R40505GW, expiry date 042020) topically in the neck administered by the owner on approximately 07112017 and 07122017. A few days after the last application the cat experienced diarrhea and later on also loss of appetite and depression. The owner called the veterinarian for advice. Because the cat started to eat little bits of food the owner decided to wait. The cat died on 24122017. No side-effects where seen after the first application of FL. |
| 30-Apr-2018 | UAE;<br>18NL000065;<br>-; Netherlands | **Species:** Canine<br>**Breed:** Spaniel (English Cocker)<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 3.50 Year(s)<br>**Weight:** 16 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Apr-2015* | 22-Apr-2018* | 1 Week(s) | D-D | As reported by the pet owner, the dog (ID name unknown, English Cocker Spaniel, intact male, 3.5 years old, 16 kg) received FRONTLINE COMBO HOND M (batch and expiry date unknown), topically between the shoulders, administered by the owner, monthly for several years. Start date is fictional. A week after the administration on 15042018 a few fleas (3 or 4) were observed on the dog. On 28042018 the dog received another pipette. Because the dog kept scratching itself the owner contacted the attending veterinarian. Stronghold (active ingredient Selamectin) was prescribed on 30042018. Owner expects lack of efficacy. |
| 01-May-2018 | UAE;<br>18NL000066;<br>-; Netherlands | **Species:** Canine<br>**Breed:** Leonberger<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 2.50 Year(s)<br>**Weight:** 50 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | 04-Apr-2018* | 06-Apr-2018* | 2 Day(s) | D-E | As reported by the owner the dog Binky (Leonberger, a neutered male, 2.5 years old, approximately 50 kg) received FRONTLINE COMBO HOND XL (batch and expiry date unknown) in the first week of April 2018, administered by the owner. Exact place of administration is unknown. Every day the owner observes multiple ticks on the dog. Almost every day the owner walks with the dog in the nearby woods. In the past the dog is treated with Vectra, no ticks were found then. Owner expects lac of efficacy. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | |
| 07-May-2018 | UAE; 18NL000072; -; Netherlands | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 11.50 Year(s)<br>**Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 30-Apr-2018 | 01-May-2018 | 1 Day(s) | D-E | Suspected lack of efficacy: As reported by the pet owner, the dog Bo (Labrador retriever, neutered male, 11.5 years old, 35 kg) received FRONTLINE COMBO HOND L (batch and expiry date unknown), topically between the shoulders, administered by the owner on 30042018. The two cats in the household received Frontline Combo Kat at the same date. Fleas were observed on the animals before the administration. Every day after the FL application fleas were found on the animals. On 02050218, on advice of the veterinarian, Vectra was applied. The following days no fleas were observed on the animals. The suspected lack of efficacy of Frontline Combo Kat is reported separately. |
| 07-May-2018 | UAE; 18NL000073; -; Netherlands | **Species:** Feline<br>**Breed:** British Shorthair<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 1.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 30-Apr-2018 | 01-May-2018 | 1 Day(s) | D-E | Suspected lack of efficacy: As reported by the pet owner, the cats Roils (British Shorthair, neutered male, 3 years old, weight unknown) and Nala (British Shorthair, neutered female, 1 year old, weight unknown) received FRONTLINE COMBO KAT (batch and expiry date unknown), topically between the shoulders, administered by the owner on 30042018. The dog in the household received Frontline Combo Hond L at the same date. Fleas were observed on the animals before the administration. Every day after the application fleas were found on the animals. On 02050218, on advice of the veterinarian, Vectra was applied and the following days no fleas were observed on the animals. The cats have no outdoor access. Linked to case 18NL000072: suspected lack of efficacy of Frontline Combo Hond L by the dog in the household. |
| 15-May-2018 | UAE; 18NL000086; -; Netherlands | **Species:** Canine<br>**Breed:** Terrier (Jack Russell)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 16.00 Year(s)<br>**Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 08-May-2018 | 12-May-2018* | 4 Day(s) | D-D | Suspected lack of efficacy: As reported by the pet owner, the dog Sammy (Jack Russell, neutered male, almost 16 years old, approximately 7 kg) received FRONTLINE SPOT ON HOND S (batch nr P21507AX, expiry date 102019), topically between the shoulders, administered by the owner on 08052018. The FL was applied because the dog has itching problems. The owner has not discovered fleas on the dog but, due to the character of the dog, close inspection of skin and coat was/is not possible. In de past the dog has received FL several times, dates are unknown. Last treatment before this was probably in January 2018. |
| 15-May-2018 | UAE; 18NL000087; -; Netherlands | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 9.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 02-May-2018* | 03-May-2018* | 1 Day(s) | D-D | Suspected Adverse Event: As reported by owner the cat Maxie (Domestic Shorthair, neutered male, approximately 9 years old, weight unknown) received FRONTLINE COMBO KAT (batch nr and expiry date unknown) topically between the shoulders administered by the owner approximately monthly for several years. After the treatment early in May 2018 the cat vomited once and a few days later a bald spot was visible at the application site. At the moment of reporting the spot is still hairless and has a diameter of 2 by 2 cm. Looking back the cat had vomited once and experienced for approximately 1.5 week hair loss at the application site after the application early in April 2018; then the symptoms were not connected to the use of FL. |

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| 17-May-2018 | UAE; 18NL000088; -; Netherlands | **Species:** Canine **Breed:** Retriever (Flat-Coat) **Sex:** M **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 35 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 04-Apr-2018* | 07-Apr-2018* | 3 Day(s) | D-E | Suspected lack of efficacy: As reported by the owner the dog Elmo (Flat-coated Retriever, intact male, 4 years old and 35 kg) received FRONTLINE SPOT ON HOND L (batch nr P21701AX, expiry date 112019) topically between the shoulders, administered by the owner, in the first week of April 2018. From several days after the treatment till now the owner discovered regularly multiple living ticks on the dog. Today the owner removed 7 ticks from the dog. |
| 18-May-2018 | UAE; 18NL000091; -; Netherlands | **Species:** Feline **Breed:** British Shorthair **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Month(s) **Weight:** 3.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 15-May-2018 | 16-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: As reported by the pet owner the cat Tiki-Tigaa (British Shorthair, neutered female, 7 months old, 3.2 kg) received FRONTLINE COMBO KAT (Batch R40103AW, expiry date 022019) topically in the neck, administered by the owner on 15052018. In the evening of 16052018 the consistency of the cats' feces was softer than normal. The following day the cat produced unformed and soft stool once. That day the cat was brought to a cat hostel for a few days. On 19052018 the cat was home again and on 20052018 the cat produced normal feces. No abnormalities were reported by the cat hostel. There has been no change in diet. The cat has no outdoor access at home. The first time the cat received FL, in March 2018, no problems were observed. |
| 22-May-2018 | UAE; 18NL000092; -; Netherlands | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.50 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 18-May-2018 | 21-May-2018 | 3 Day(s) | D-E | Suspected lack of efficacy: As reported by the owner, the cat Bambina (Domestic Shorthair, neutered female, 3.5 years, approximately 4 kg) received FRONTLINE COMBO KAT (Batch no and expiry date unknown), topically in the neck, administered by the owner on 18052018. Multiple fleas were observed on the cat before the treatment. On 21052018 there were still a few fleas visible on the cat. The cat has outdoor access. It was the first time that the cat was treated with FL. It was in 2018 the first anti-flea treatment used on the cat. |
| 24-May-2018 | UAE; 18NL000095; -; Netherlands | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 3.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 23-May-2018 | 23-May-2018 | 0 Day(s) | D-C | As reported by UPDATE 01-06-2018 a (almost graduated) vet (end UPDATE 01-06-2018) cat Bella (neutered domestic shorthair female, 1 year of age, weight 3.6kg, outdoor cat) received in the morning of the 23th of May one pipet Frontline Combo cat (batchnr and expiry date unknown) on the skin between the shoulderblades. In the afternoon the cat experienced tremors of the head and limbs and in the evening also of the body. She was administered diazepam and received intravenous 0.9% NaCl-drip. During the evening she was sent home. On the 28th of May she was still a bit atactic but no tremors anymore. |
| 01-Jun-2018 | UAE; 18NL000099; -; Netherlands | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products** | 26-May-2018 | 26-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by owner the cat Drentel (Domestic Shorthair, neutered male, approximately 12 years old, 3 kg) received FRONTLINE SPOT ON KAT (batch R21306AX, expiry date 072020) topically in the neck administered by the |

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| | | **Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 12.00 Year(s)<br>**Weight:** 3 kg | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | owner on 26052018. In the evening the owner detected a hairless spot from 2 by 1 centimeter on the application site. On 01072018 the affected spot is still there but only visible if overhanging hairs is held aside. |
| 01-Jun-2018 | UAE; 18NL000100; -; Netherlands | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 12.00 Year(s)<br>**Weight:** 2 kg | 1 | 1 | 1 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 27-May-2018 | 27-May-2018 | 0 Day(s) | D-A | Suspected Adverse Event: As reported by owner the cat Dartel (Domestic Shorthair, neutered female, approximately 12 years old, 2 kg) received FRONTLINE SPOT ON KAT (batch nr R21306AX, expiry date 072020) topically in the neck administered by the owner on 27052018. A few hours later the cat experienced weakness in the hind legs. The next days the walking improved and because the cat continued to drink the owner did not visit a veterinarian. Since 310502018 the cat was missing. The next day the cat was found by neighbors and was transported to a veterinary clinic. The cat expericienced reduced awareness, was very skinny and severely dehydrated.Tthe cat was euthanized by the veterinarian. No blood work or autopsy has been performed. According to the owner the cat had lost weight in the last period but did not seem sick. |
| 06-Jun-2018 | UAE; 18NL000102; -; Netherlands | **Species:** Canine<br>**Breed:** Border Collie<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 19 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-May-2018 | 01-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the veterinarian technician the dog Mika (Border Collie, neutered female, born 17112011, 19 kg) received FRONTLINE SPOT ON HOND M (batch and expiry date unknown) R40103AW, topically between the shoulders, administered by the owner on 01052018. A few hours later the dog experienced listlessness and lack of appetite. In the night the dog produced watery stool. Complete recovery was seen after 2 days. The dog has received FL several times a year from May 2012 till recently. After every application the dog developed the same symptoms: listlessness, lack of appetite and diarrhea. The owner thought that this was normal and has only recently reported the side effects |
| 11-Jun-2018 | UAE; 18NL000104; -; Netherlands | **Species:** Canine<br>**Breed:** Fox Terrier<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 16.00 Year(s)<br>**Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** - | 22-May-2018 | 22-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: As reported by the veterinarian technician the dog Diezel (Fox Terrier crossbred , intact male, 16 years old, approximately 10 kg) received FRONTLINE COMBO HOND M (batch and expiry date unknown), topically in the neck, administered by the owner on 22052018. Within an hour the dog experienced general pruritus. The itching is the most intense on the first day. Complete recovery is seen in a few days. The dog has received FL several times a year from September 2017 till recently, and the general itching has been observed after at least 1 earlier application. |
| 11-Jun-2018 | UAE; 18NL000105; -; Netherlands | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the** | 23-May-2018* | 26-May-2018* | 3 Day(s) | D-E | Suspected lack of efficacy: As reported by the owner the dog Luna (Crossbred, neutered female, 4 years old, approximately 7 kg) received FRONTLINE SPOT ON HOND S (batch and expiry date unknown) topically between the shoulders, administered by the owner on approximately 23052018. In the first week after the application 2 ticks were removed from the dog. After a walk in the woods on 10062018 within 24 hours 5 ticks were found on the dog. Unknown if all the ticks were still alive. |

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| | | | | | | **product used ok?:** Yes | | | | | |
| 12-Jun-2018 | UAE; 18NL000106; -; Netherlands | **Species:** Canine **Breed:** Dachshund **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Aug-2016* | 03-Sep-2016* | N/A | D-E | Suspected lack of efficacy: As reported by the pet owner, the dog (ID name unknown, Wirehaired Dachshund, female, 2 years old, 5 kg) received FRONTLINE COMBO HOND S (batch and expiry date unknown), topically between the shoulders, administered by the owner, regularly. Start date is fictional. First the FL was used every 6 weeks, since February 2018 the dog is treated every 4 weeks. Last treatment was on 15052018. Fleas have been seen on the dog since her arrival in the household in 2016. Every day approximately 4 small fleas and flea dirt are observed on the dog. |
| 12-Jun-2018 | UAE; 18NL000107; -; Netherlands | **Species:** Canine **Breed:** Mixed Breeds / various **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 1.6 - 20 kg | 5 | 5 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Off label use / Indication) | 31-Mar-2018* | 15-May-2018* | N/A | D-E | Suspected lack of efficacy: As reported by the pet owner 4 dogs (2 Shih Tzu, 2 Crossbred, 1 Chihuahua, weight between 1.6 and 8 kg, more information not available) received FRONTLINE COMBO HOND S (batch and expiry date unknown), topically between the shoulders, administered by the owner, monthly form end of March 2018 till 30052018. The fifth dog (Crossbred dog, weight between 10 and 20 kg) received FRONTLINE COMBO HOND M (batch and expiry date unknown) on the same dates. Since May 2018, by every inspection, the owner detected approximately 5 fleas on all dogs. No fleas are found on the, with Frontline Combo Kat treated, Persian cat in the household. The animals have been treated with FL in previous years, but never during winter months. The Frontline combo Hond S is applied on the Chihuahua weighing 1.6 kg, while FL should not be used on dogs weighing less than 2 kg. |
| 15-Jun-2018 | UAE; 18NL000109; -; Netherlands | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 03-Jun-2018* | 06-Jun-2018* | 3 Day(s) | D-D | Suspected Adverse Event: As reported by owner the cat Rossie (Domestic Shorthair, neutered male, 6 years old, weight unknown) received FRONTLINE COMBO KAT (batch R40103AW, expiry date 122019) topically between the shoulders administered by the owner on approximately 03062018. A few days later a hairless spot on the application site was observed. At the moment of reporting the spot is still hairless and has a diameter of approximate 1,5 cm. Thinking back transient hair at the application site had occurred also after the previous administration in March 2018. In previous years no problems were observed after the use of FL. |
| 20-Jun-2018 | UAE; 18NL000112; -; Netherlands | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous | 03-Jun-2018* | 07-Jun-2018* | 4 Day(s) | D-D | Suspected Adverse Event: As reported by owner the cat Duif (Domestic Shorthair, neutered female, 12 years old, weight unknown) received FRONTLINE COMBO KAT (batch P40617AW, expiry date 042019) topically in the neck administered by the owner on approximately 04062018. General pruritus, due to the presence of multiple fleas, was observed before the application of FL. A few days after the use of FL the cat experienced application site hair loss, itching and skin irritation. On 20062018 the spot is still hairless and measures approximately 5 by 1,5 cm. In previous years no problems were observed after the use of FL. |

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| | | | | | | **Was the product used ok?:** Yes | | | | | |
| 21-Jun-2018 | UAE; 18NL000113; -; Netherlands | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** - **Age:** 8.00 Week(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** FIPRONIL SPOT ON CAT; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 27-Apr-2018* | 14-Jun-2018* | 1 Week(s) | D-E | Suspected lack of efficacy: As reported by the pet owner, the cat Shadow (Domestic Shorthair, a neutered male, 19 years old, approximately 3 kg) received FRONTLINE SPOT ON KAT (batch and expiry date unknown) topically between the shoulders, administered by the owner, approximately 8 weeks ago. The cat Ziggy (Domestic Shorthair, male, approximately 8 weeks old) was treated with FRONTLINE SPRAY (batch and expiry date unknown) on the same date. Spray is dosed on weight, but exact weight was unknown. Ziggy was introduced in the household a week earlier and had fleas then. In June Shadow received another pipette and Ziggy was sprayed again. From a week after the last treatment till now every day multiple fleas are found on the cats. The cats have outdoor access, but stays mainly at home. |
| 16-May-2018 | UAE; 18NO000016; -; Norway | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 26-Apr-2018 | 27-Apr-2018 | 1 Day(s) | D-D | The approximately 5 years old neutered male cat of mixed breeds, 6 kg, was treated with Frontline Vet topical on 26.04.2018 as tick prevention. 12 hours later the cat started to itch so much that it started to bleed and developed alopeci and erythema. The reaction lasted 24 hours. The cat was treated with Prednisolone 5 mg 1 tabl sid for 2 days and was washed. The cat has recovered. |
| 15-Jun-2018 | UAE; 18NO000018; -; Norway | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 4.9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 14-Jun-2018 | 15-Jun-2018 | 1 Day(s) | D-C | The neutered male cat (breed unknown), weight app. 4.9 kg, born 01.09.2013, was treated with Frontline vet spot-on for cats on 14.06.2018 (administration way unknown) in the evening. The cat was let outside during the night. The next morning (15.06.2018) at the returned the cat was trembling, which get worse at light/sounds. The cat has difficulty to walk and mydriasis. The cats is chewing with the mouth, but there is no hypersalivation and the clinical exam of the mouth at the veterinarian clinic is without remarks. Blood sample at the veterinarian clinic: potassium low but it could be normal for the in-house laboratory, other values within normal limits. The cat was washed to remove Frontline vet. The cat was treated with fluid therapy (RA), Stesolid (diazepam 4 mg rectal 00 pm and 2 mg iv 3 pm) and 0,1 ml propofol at 1.30 pm. The outcome of the reaction is unknown. |
| 03-Apr-2018 | UAE; 18NZ000129; -; New Zealand | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 26-Mar-2018 | 26-Mar-2018 | 0 Day(s) | D-D | As reported by the owner he treated his 2 Domestic Short Hair cats with FRONTLINE Plus for Cats (FLP) on 26 March 2018. In the last couple of days the owner says the cats have been covered in live fleas. Both cats spend time outside and there are stray cats in the neighbourhood. Prior to the FLP the cats were treated with BROADLINE 5 weeks earlier and before that they were dosed with Advantage every 5 weeks. |

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| 05-Apr-2018 | UAE; 18NZ000130; -; New Zealand | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** - **Age:** - **Weight:** 3 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Mar-2018* | 01-Mar-2018* | N/A | D-E | As reported by the owner, FRONTLINE PLUS for cats (batch: R40416AL and expiry 02/2020) was applied to a 3kg female domestic shorthair cat on approximately 01 March 2018 and again on 22 March 2018. Previous dates of treatment are not available and a different product was used.The owner is seeing approximately 10 fleas on the cat and it spends quite a lot of time outside in the garden and under the deck. |
| 05-Apr-2018 | UAE; 18NZ000131; -; New Zealand | **Species:** Feline **Breed:** British Shorthair **Sex:** - **Sex qualifier:** - **Age:** 12.00 Year(s) **Weight:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2015* | 31-Mar-2018* | 17 Day(s) | D-D | As reported by the owner, a 12 year old British Blue cat was treated with FRONTLINE PLUS for Cats at 5 weekly intervals, the last treatment date was 14 March 2018. The cat spends most of its time indoors but has been extremely itchy and losing lots of fur over the past 7 days. The owner is seeing fleas on the cat but she is not getting bitten herself. There have been no changes to the diet or the husbandry conditions of the cat. |
| 11-Apr-2018 | UAE; 18NZ000133; -; New Zealand | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 15-Mar-2018 | 15-Mar-2018 | 0 Day(s) | D-E | As reported by the owner she treated her 2 cats with FRONTLINE Plus for Cats (FLP) on 15 March 2018. Since treatment she has continued to see many live fleas on both cats. Prior to FLP the cats were treated monthly with Evance. A few days ago there were so many fleas that she decided to treat with Evance and all the fleas died and have not been a problem since. The cats have unlimited access outdoors and under the house. There is also a stray cat that hangs around the neighbourhood. |
| 12-Apr-2018 | UAE; 18NZ000134; -; New Zealand | **Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 32 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** - | 01-Feb-2018* | 01-Feb-2018* | N/A | D-E | As reported by the owner she treated her male 32kg dog with FRONTLINE Plus for Large Dogs (FLP) on approximately 1 February, 1 March and 1 April 2018. Batch P621088R expiry 08/2019. She is still seeing 2-3 fleas each day on the dog. The owner is not getting flea bites in the house. She has no other pets and does not see a lot of wildlife in the garden. The dog has unlimited access outdoors. |
| 17-Apr-2018 | UAE; 18NZ000140; | **Species:** Canine **Breed:** Shetland | 1 | 1 | 0 | **Product used:** FIPRONIL | 01-Mar-2018* | 01-Mar-2018* | N/A | D-E | As reported by the veterinary nurse, an owner treated her 1.5 year old, male neutered, Sheltie called Finn with FRONTLINE Plus for |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | -; New Zealand | Sheep Dog (Sheltie)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 1.50 Year(s)<br>**Weight:** Unknown | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** - | | | | | Small dogs (FLP) in March and April (exact dates unknown). Batch R61907 expiry 08/2020. The nurse said she is a regular customer however they had no purchase history for her except for this one recent 3-pack of FLP. The owner returned for a refund because she was not happy she was still seeing fleas on the dog. |
| 23-Apr-2018 | UAE; 18NZ000148; -; New Zealand | **Species:** Canine<br>**Breed:** Cavalier King Charles<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** -<br>**Weight:** 20 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Feb-2018 | 10-Apr-2018 | 9 Day(s) | D-E | As reported by the owner, her approximately 20kg poodle x cavalier king charles spaniel was treated topically with FRONTLINE PLUS on 1 February 2018 by the owner and again on 1 April 2018. Over the last 2 weeks the owner has been seeing many fleas on the dog. There is also a cat in the household which has been treated regularly with flea product. |
| 26-Apr-2018 | UAE; 18NZ000150; -; New Zealand | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 4 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 23-Apr-2018 | 23-Apr-2018 | 0 Day(s) | D-D | As reported by the owner he treated her approximately 4kg female Domestic Short Hair cat with FRONTLINE Plus for Cats (FLP) on 23 April 2018. Since treatment the cat is still very itchy and covered in fleas, flea dirt and possibly flea eggs. Cat is indoor onli and owner is not getting any flea bites on himself. There is also a dog in the household that was also treated with FRONTLINE Plus (for dogs) on 23 April 2018. Both animals have had no flea treatment for the previous 3 months. |
| 25-Apr-2018 | UAE; 18NZ000151; -; New Zealand | **Species:** Canine<br>**Breed:** Schnauzer<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Month(s)<br>**Weight:** 8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** - | 01-Apr-2018* | 01-Apr-2018* | N/A | D-D | As reported by the owner she treatted her approximately 3 month od, 8kg Schnauzer puppy with FRONTLINE Plus for Small Dogs twice in April, exact dates unclear. Over a five day period following treatment the dog was covered in fleas. The owner was not getting bitten and the dog was not taken outside during this period. There is also a cat in the household which is treated monthly with FRONTLINE Plus for Cats. The cat doesn't appear to have any fleas. |
| 30-Apr-2018 | UAE; 18NZ000155; -; New Zealand | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** M<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | 13-Mar-2018* | 13-Mar-2018 | 0 Day(s) | D-D | As reported by the owner she purchased a 3-pack of FRONTLINE Plus for Large Dogs (20-40kg) from a vet clinic 6 weeks ago. She has 2 cats weighing 6-7kg and 1 dog weighing 5.8kg. The vet told her to measure out 0.6mL of the product for the cats and 1.2mL of product for the dog, which she did with a medical syringe when she |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** -<br>**Weight:** 5.8 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Overdose) | | | | | treated the animals on approximately 13 March 2018. The dog is a male Miniature Poodle weighing 5.8kg. Since treatment with the FLP the owner has continued to see fleas on the dog. She got 16 live fleas off him the other day. He is normally treated with Advantage, but only when the owner sees fleas. The last treatment before this FRONTLINE Plus was around Christmas 2017. The two cats are Persians and since treatment she has seen flea dirt on them but not fleas, as their fur is very thick and hard to look through. Refer to case 18NZ000156 for the cats. |
| 30-Apr-2018 | UAE; 18NZ000156; -; New Zealand | **Species:** Feline<br>**Breed:** Persian (No Further Description)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 6 - 7 kg | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Overdose) | 13-Mar-2018* | 13-Mar-2018* | 0 Day(s) | D-D | As reported by the owner she purchased a 3-pack of FRONTLINE Plus for Large Dogs (20-40kg) from a vet clinic 6 weeks ago. She has 2 Persian cats weighing 6-7kg and 1 dog weighing 5.8kg. The vet told her to measure out 0.6mL of the product for the cats and 1.2mL of product for the dog, which she did with a medical syringe when she treated the animals on approximately 13 March 2018. Since treatment with the FLP the owner has continued to see flea dirt on the cats, although not fleas as they have a thick haircoat so it is hard to look through. The cats are normally treated with Advantage, but only when the owner sees fleas. The last flea treatment before this FRONTLINE Plus was around Christmas 2017. Refer to case 18NZ000155 for the dog. |
| 08-May-2018 | UAE; 18NZ000160; -; New Zealand | **Species:** Canine<br>**Breed:** Pomeranian<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 3.5 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 29-Apr-2018 | 29-Apr-2018 | 0 Day(s) | D-D | As reported by the owner she treated her male, approximately 3.5kg Pomeranian with FRONTLINE Plus for Small Dogs on 29 April 2018 because she was seeing fleas on the dog. Since treatment the owner has been getting bitten by fleas and the dog is very itchy. This is the first flea treatment the Pomeranian has had in the six months it has been in this household. There is another dog that sleeps outside in a kennel, and that dog has been treated with NEXGARD. |
| 08-May-2018 | UAE; 18NZ000161; -; New Zealand | **Species:** Canine<br>**Breed:** Canine Other<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 10 | 4 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 09-Apr-2018 | 09-Apr-2018 | 0 Day(s) | D-D | As reported by the owner she treated her 10 working farm dogs with FRONTLINE Plus for Large Dogs on 9 April 2018 because the dogs were scratching. Since treatment 4 of the dogs are still very itchy although she has not seen any actual fleas. The dogs are itchy around the neck and stomach. Prior to April the dogs were not treated for fleas at all. |
| 09-May-2018 | UAE; 18NZ000163; -; New Zealand | **Species:** Canine<br>**Breed:** -<br>**Sex:** -<br>**Sex qualifier:** -<br>**Age:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | 01-Jan-2018 | 02-May-2018* | 0 Day(s) | D-D | As reported by the owner, FRONTLINE PLUS FOR DOGS (unknown batch and expiry) was applied to an approximately 5 kg dog on 2 May 2018. The dog spends most of its time in the house and the owner is seeing more than 5 fleas on the dog in particular around the tail base. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 5 kg* | | | | **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | |
| 09-May-2018 | UAE; 18NZ000165; -; New Zealand | **Species:** Canine **Breed:** Bichon Frise **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 8 kg | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose) | 10-Apr-2018 | 10-Apr-2018 | N/A | D-D | As reported by the owner, three dogs were treated with FRONTLINE PLUS FOR DOGS (unknown batch and expiry) by the owner on 10 April 2018 and again on 3 May 2018. Previous flea treatment was applied during November 2018 with a different product. The owner is still seeing 2-3 fleas on the one of the dogs, 'Lucy' a 8kg female bischon frise. All of the dogs spend time in the house and garden. |
| 15-May-2018 | UAE; 18NZ000168; -; New Zealand | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 16-Apr-2018 | 16-Apr-2018 | N/A | D-E | As reported by the owner he treated his cat with FRONTLINE Plus for Cats on 16 April 2018 and again on 9 May 2018 because he was still seeing fleas. Prior to April the cat was not on any flea control. The cat was infested with fleas when treatment began. |
| 21-May-2018 | UAE; 18NZ000173; -; New Zealand | **Species:** Canine **Breed:** Staffordshire Terrier **Sex:** M **Sex qualifier:** - **Age:** 4.00 Year(s) **Weight:** 18.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Mar-2014* | 14-Mar-2018 | 2 Day(s) | D-C | As reported by the attending veterinarian, the owner treated their 4 year old, approximately 18.6kg, male intact Staffordshire Bull Terrier Jed with FRONTLINE Plus for Medium Dogs (FLP) on 12 March 2018. Two days later on 14 March the dog had a seizure. On 17 April 2018 the dog had a second seizure. The dog has no history of seizures. It has been treated with FLP once previously with no reaction. Biochemistry and CBC blood tests done on 14 March showed no abnormalities. Following a phone call to the clinic on 22 May 2018, a nurse confirmed the dog has had no further seizures since 17 April 2018. |
| 22-May-2018 | UAE; 18NZ000179; -; New Zealand | **Species:** Feline **Breed:** - **Sex:** - **Sex qualifier:** - **Age:** - **Weight:** - | 3 | 3 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / | 15-Apr-2018* | 15-Apr-2018* | 0 Day(s) | D-E | As reported by the owner, FRONTLINE PLUS for cats was applied topically to 3 cats by the owner on approximately 15 April 2018. The cats were normally treated with a different flea (BROADLINE) treatment on a regular basis but they did had fleas at the time of treatment. After application with FRONTLINE PLUS the cats continued to have fleas and were still pruritic. The owner used a different product and then the numbers of fleas reduced again . |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | |
| 23-May-2018 | UAE;<br>18NZ000180;<br>-; New Zealand | **Species:** Canine<br>**Breed:** Maltese<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** -<br>**Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Mar-2018* | 01-Mar-2018* | N/A | D-D | As reported by the owner, her 5kg maltese male dog was treated with FRONTLINE PLUS For Small dogs (unknown batch and expiry)topically by the owner on approximately 1 March 2018 and then again on 1 April 2018. During this period she continued to see many fleas on the dog and the dog was very pruritic. Prior to the FRONTLINE treatment the owner had been dosing the dog at an incorrect dosing interval with a different product every 3 months. The owner has since treated the dog with an oral parasiticide and the flea infestation has resolved. |
| 27-May-2018 | UAE;<br>18NZ000185;<br>-; New Zealand | **Species:** Canine<br>**Breed:** -<br>**Sex:** -<br>**Sex qualifier:** -<br>**Age:** -<br>**Weight:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 26-May-2018 | 26-May-2018 | 0 Day(s) | D-E | As reported by the owner, FRONTLINE PLUS FOR SMALL DOGS (unknown batch and expiry)was applied topically to a dog by the owner on 26 May 2018. At the time of treatment the owner was seeing many fleas in the house and was continuing to see fleas after dosing. She had previously used a different product but there had been a gap in her dosing frequency. |
| 28-May-2018 | UAE;<br>18NZ000186;<br>-; New Zealand | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 17 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Apr-2010* | 01-Apr-2018* | 0 Day(s) | D-E | As reported by the owner she has been treating her 17kg male dog with FRONTLINE Plus for medium dogs every 6 weeks for the past 8 years. Since April this year the dog has had a consistently high flea burden, with approximately 20 fleas a day being seen on him. The owner was not getting any flea bites on herself. The dog does spend a lot of time outdoors and the owner has seen fleas in the garden outside. There is also a cat in the household that is treated with FRONTLINE Plus for Cats every 6 weeks that doesn't seem to be having a problem with fleas. In early May the owner tried a different topcial flea product (brand unknown) on the dog and then she saw no more fleas. |
| 05-Jun-2018 | UAE;<br>18NZ000197;<br>-; New Zealand | **Species:** Canine<br>**Breed:** -<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 16-May-2018 | 16-May-2018 | 0 Day(s) | D-E | As reported by the owner, FRONTLINE PLUS FOR SMALL DOGS (unknown batch and expiry) was applied topically to 'Wills' a 4 year old male neutered dog on 16 May 2018 by the owner. At the time of treatment the owner saw 1-2 fleas on the dog. The owner has continued to see a couple of fleas on the coat of the dog but he is not itchy. The owner acquired the dog 2 months ago from another owner and the date of previous treatment is unknown. There are no other animals in the household. The owner is continuing to see a couple of fleas on the dog. |

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| | | | | | | **ok?:** Yes | | | | | |
| 07-Jun-2018 | UAE; 18NZ000200; -; New Zealand | **Species:** Feline **Breed:** Birman **Sex:** F **Sex qualifier:** - **Age:** - **Weight:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Contraindication per label) | 01-Jan-2018* | 18-May-2018 | N/A | D-E | As reported by the owner, a female birman cat was treated with FRONTLINE PLUS FOR CATS(unknown batch and expiry) on 2 May 2018. The treatment prior to that was applied on 18 May 2018 and at 6-8 week intervals. The owner continues to see a small number of fleas on the cat. |
| 18-Jun-2018 | UAE; 18NZ000215; -; New Zealand | **Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Seresto Collar; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 07-Jun-2018* | 10-Jun-2018* | 3 Day(s) | D-D | As reported by the attending veterinarian, the owner applied FRONTLINE Plus for Small Dogs (FLP), to her 4 year old, female spayed, Maltese Terrier Sophia, on approximately 7 June 2018. The dog was also wearing a Seresto Collar at the time of FLP application. This was the second Seresto collar she had used within a month as she thought the first one 'wasn't working'. A few days after FLP application there was a skin reaction visible at the site of application at the back of the neck. The dog was seen by the vet on 15 June who reported an ulcerative, weeping patch at the site of application and papules along the back as well as pruritus and a reddened appearance to the skin. The vet prescribed a course of Clavulox and Prednisone for the skin and also administered an Arthropen Vet Injection for the dog's pre-existing arthritis. The consult for the Arthropen Injection was pre-planned prior to the flea treatments. |
| 15-May-2018 | UAE; 18PL000019; 83-000; Poland | **Species:** Canine **Breed:** Bernese Mountain Dog **Sex:** U **Sex qualifier:** Unknown **Age:** 7.00 Month(s) **Weight:** 33 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Yes | 17-Apr-2018* | 15-May-2018* | 0 Day(s) | D-E | Suspected Lack of Efficacy: as reported by distibutor with whom owner contacted by phone, a dog, 7 months old, 33kg, Bernese Mountain dog breed, was treated with FRONTLINE SPOT ON for DOGS, dosage 20-40 kg, administered by the owner, on an unknown date (15 May 2018 chosen by default). It was the 2nd exposure to this product, the first dose was given 4 weeks ago approximately. After second use, on an unknown time to onset (15 May 2018 chosen by default), the owner reported that the product didn't work, despite following instruction on the leaflet (Owner didn't wash the dog, and didn't change the place of stay). The owner claimed that after second use of FRONTLINE SPOT ON FOR DOGS, she found 8 ticks on her dog. The application's site is unknown. This is the extent of information available. |
| 26-Apr-2018 | UAE; 18PT000019; -; Portugal | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** - **Age:** - **Weight:** Unknown | 2 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown | 01-Apr-2018* | 01-Apr-2018* | 0 Day(s) | D-B | Suspected Adverse Reaction: a cat (unknown signalment) was treated with FRONTLINE SPRAY (BN, exp date unknown) on an unknown date (01 Apr 2018 was chosen by default). On an unknown time after product administration, the cat experienced nervous symptoms for more than one week after administration, with hyperesthesia, opistotonus, lack of proprioception on the 4 limbs and mydriasis. The cat was also not eating and had weak intestinal peristaltic moves (no reaction after enema). This is the extent of information available. UPDATE MAH 18 May 2018: as reported by the attending vet, the cat is a male and the product had been administered topically by the owner. The reaction was treated |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | to Company | | | | | (no information concerning the terapeutic) and the cat stayed in observation for at least 24 hours. Frontline spray had been administered by the pet owner to 2 cats (one with suspected reation, the other without symptoms). |
| 04-Apr-2018 | UAE; 18SE000051; -; Sweden | **Species:** Canine **Breed:** Hound Breeds (200 Series) **Sex:** U **Sex qualifier:** Unknown **Age:** 2.50 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | Jan-2018 | Jan-2018 | 0 Day(s) | D-D | The 2.5 years old hounting dog (Drever) was treated with Frontline Spray Vet due to lice by the owner in JAN 2018. The dog kept itching despite the lice was gone. 6 weeks later the owner decided to treat the dog again assuming that the dog was itching because of lice. Long time after the dog is still icthing and the fur has become dry and with dandruff.<br>The owner toke the dog to the veterinarian and the dog was tested positiv on allergy test (Typer and exact result are unknown).<br>According to the owner the dog is allergic to all most everything in the surroundings. At the time of reporting the dog has not recovered. |
| 11-Apr-2018 | UAE; 18SE000056; -; Sweden | **Species:** Feline **Breed:** Feline Other **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 4.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** Atopica; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 12-Jun-2016 | 12-Jun-2016 | N/A | D-D | SE-SEMPAV-2016-00378:<br>An adverse event report, from a veterinarian, received by the MPA on August 05, 2016, regarding a cat, neutered female, domestic short-hair, 7 years old and bodyweight 4.7 kg.<br><br>On June 12, 2016, the cat was treated with Frontline, spot-on solution, strength unknown, batch no unknown, one dose, as prevention against ticks. Concomitant medication; Atopica 25 mg, capsule, due to atopy. After administration of Frontline the cat got skin ulcers in the neck and head region, but recovered after treatment with cortinsone. The cat has had previous treatments with Frontline, but then received treatment with Medrol at the same time. |
| 17-Apr-2018 | UAE; 18SE000063; -; Sweden | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** - **Age:** 10.00 Year(s) **Weight:** 5 kg | 3 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** Program vet. 133 mg; **Route:** unknown **Was the product used ok?:** Unknown to Company | 28-Mar-2018 | 29-Mar-2018 | N/A | D-C | SE-SEMPAV-2018-00153:<br>A serious adverse event report from a veterinarian received by the MPA on April 03, 2018, regarding a cat, Domestic Short-hair, male, 10 years old and bodyweight 5 kg. 3 cats were treated but only one had adverse reactions.<br><br>The cat was treated with Frontline vet., spot-on solution, 100 mg/ml, 1 dose and Program vet. oral suspension, 133 mg, 1 dose on March 28, 2018, due to lice and fleas. On March 29, 2018 the cat got convulsions, was lying on its back and shaking, rolling around and waved his legs. The cat was foaming at its mouth. The seizures lasted for 2-3 minutes and were repeated every 45 minutes. The cat seemed to be conscious. After the first times the cat recovered quickly but became more tired for every seizure. The cat was brought to the clinic. The cat was dull with reduced mental function and dyspnoea, after 1-1.5 hour the cat improved.. Blood samples were normal, x-ray showed nothing abnormal with hearts and lungs, possibly a densification cranially but that was difficult to determine due to overweight. The cat also possibly had a mild enlarged kidney and small amounts of liquid in the abdominal cavity.<br>Adverse reaction from treatment could not be ruled out according to the reporting veterinarian.<br>The cat was treated with Stesolid (diazepam) injections and tablets but at the time of report the cat had not yet recovered.<br>2018-04-17: FU from CA where veddra-code "Foam in the mouth" has been changed to "Foaming at mouth". |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 05-Apr-2018 | UAE; 18SE000064; -; Sweden | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 3 | 3 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | Feb-2018* | Feb-2018* | N/A | D-E | A cat owner reported on the 5-APRIL-2018 that three of her cats of unknown breed, weight and age had received one dose of Frontline (product not specified) for lice and flea control. The products had been given the first time many weeks before the date of reporting. Four weeks after the first use of Frontline the owner gave the cats Frontline again and reports the product had no effect. |
| 24-Apr-2018 | UAE; 18SE000071; -; Sweden | **Species:** Canine **Breed:** Chinese Crested **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 19-Apr-2018 | 19-Apr-2018 | 0 Day(s) | D-C | On the 17-APRIL-2018 an owner of a Chinese Crested female dog, weight 7 kg sees a tick stuck on the dog. On the 19-APRIL-2018 the dog is treated with Frontline vet. 100 mg/ml spot-on 1 pipette for dogs weighing 7-10 kg (estimated dosage 0.67 ml). Immediately after treatment the dog get hyperexcitated and shakes a lot, the heartbeat goes up very high according to the owner. For 24 hours the only thing the owner could get the dog to consume was water mixed with electrolytes, water with salt and sugar. The first faeces after the application of Frontline was watery yellow diarhea-like. After that the stoll was normal.<br>After 24 hours on the 20-APRIL-2018 the dog had recovered. In season 2017 the dog had received tablets of unknown brand and no sideffects had shown. |
| 02-May-2018 | UAE; 18SE000073; -; Sweden | **Species:** Canine **Breed:** Pug **Sex:** M **Sex qualifier:** Unknown **Age:** 12.00 Year(s) **Weight:** Unknown | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 29-Apr-2018 | 29-Apr-2018 | 0 Day(s) | D-A | The 12 years old male pug dog was treated with Frontline Comp (strength unknown so chosen by default) on sunday morgning 29.04.2018. Sunday night the owner was waked up because the dog is having a a kind of seizure. The dog is stiff in the hindlegs, according to the owner the dog is not able to stand but is at the same time walking in circles. The owner takes the dog to the animal hospital, where the dog was euthanalized. MAH has offered to have the dog autopsied, but the dog was already cremated. |
| 04-May-2018 | UAE; 18SE000074; -; Sweden | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 2018* | 2018* | 0 Day(s) | D-D | A very brief report received by a pharmacist how had been in contact with the owner:<br>A cat (breed, gender, age, weight unknown) was treated with Frontline Vet for cat. (dose is unknown). Afterward the cat lost the fur and the skin got irritated at the application site. There is no further information received in regards whether the cat was treated or if it has recovered. |
| 07-May-2018 | UAE; 18SE000075; -; Sweden | **Species:** Canine **Breed:** Small crossbred (<10 Kg) **Sex:** M **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products | 30-Apr-2018* | 30-Apr-2018* | 0 Day(s) | D-E | A brief report received from social media:<br>The small mixed breed male dog (age and weight unknown) was treated with Frontline Vet for dog <10 kgs for some time ago. Since the date of treatment is unknown, MAH has approximated to a week before reporting. During the last week the owner has found 6 tick on the dog. No more information has been received. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | **Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | |
| 30-Apr-2018 | UAE; 18SE000078; -; Sweden | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 27-Apr-2018 | 30-Apr-2018* | 3 Day(s) | D-D | A brief report recieved by the animal owner:<br>A cat of unknown breed, weight, sex and age was given 1 pipette, 0.5 ml of Frontline Vet.100 mg/ml on the 27-APRIL-2018. On the 30-APIL-2018 the owner contacted the company reporting that after administration the cat had lost some fur at the application site in the neck. |
| 04-May-2018 | UAE; 18SE000080; -; Sweden | **Species:** Canine<br>**Breed:** Canine Other<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 9.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 26-Aug-2017* | 26-Oct-2017 | 30 Day(s) | D-C | On the 4-MAY-2017 it was reported that a female Finnish spitz, weight 9.5 kg, had received Frontline (product and dose unspecified) in the period of approximately from 26-AUG-2017 to 26-SEP-2017 (two times four weeks apart). On the 26-OCT-2017 the owner came to the veterinarian clinic and told the veterinarian that the dog had loosing its voice (hoarse) when barking for the last three months and it had been 4 weeks since last dosage was given. Theloss of voice is less prominent in the morning and gets worse up at the day. At sedation the veterinarian discovers a swollen epiglottis which seems like an emfysem at palpation with peang. Clinical values:wnl. An inflammation is suspected near the epiglottis. The dog was treated with Prednisolon, 1x10 mg prednisolone sid 14 days, 0.5x10 mg prednisolone sid 7 days, Axilur and recommended rest. At the control vist on the 06-NOV-2017 the dog was a little better but the owner has had difficulties making the dog quiet.X-ray revealed epiglottis emfysema, thorax wnl. Continues with prednisolon. On the 04-DEC-2017 the dog now has breathing problems on/off when eating and drinking. On the 26-APRIL it was decided to contact the company asking if there is connection to Frontline treatment as the dog received the treatment a couple of days before the signs of loosing voice appeared. At the same time it was reported that the dog was okay again. |
| 08-May-2018 | UAE; 18SE000082; -; Sweden | **Species:** Canine<br>**Breed:** Cavalier King Charles<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 11 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 07-May-2018* | 07-May-2018* | 0 Day(s) | D-D | A brief report received from social media:<br>The 5 years old male Cavalier King Charles Spaniel, 11 kg, was treated with Frontline vet 100 mg/ml at 9 am. The exact strenght/dose and date is unknown. The owner left the dog alone from 10 am to 2 pm. When the owner left the dog, the dog seems a bit irritated. When the owner returned the dog is itching and has itch so much that he has lost some of his fur. The owner washed the dog and the dog got it a little better, but still felt irritated. The outcome of the reaction is unknown. |
| 08-May-2018 | UAE; 18SE000084; -; Sweden | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other | 20-Apr-2018 | 27-Apr-2018 | 1 Week(s) | D-D | A two year old neutered male cat, weight approximately 3 kg was given Frontline Spot-on solution 100 mg/ml on 20-APRIL-2018. On 27-APRIL-2018 within a week after the single administration larger ticks were found on the cat by owner and again on the 01-MAY-2018 two-three smallere ticks were found in the skin of |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex qualifier:** Neutered<br>**Age:** 2.00 Year(s)<br>**Weight:** 3 kg | | | | products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | the cat. The owner told the pharmacist that the product did not work as intended and the pharmacist contacted the company. |
| 15-May-2018 | UAE; 18SE000086; -; Sweden | **Species:** Feline<br>**Breed:** British Shorthair<br>**Sex:** X<br>**Sex qualifier:** Mixed<br>**Age:** 1.00 Year(s)<br>**Weight:** 3 - 6 kg | 4 | 4 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** - | 29-Apr-2018 | 29-Apr-2018 | N/A | D-E | 4 British shorthair cats ( 1x 1 years old male 5-6 kg and 3 x 3-12 years old neutered females 3-4 kg) were treated with Frontline Vet. spot-on, batch no R21305AX, on 29.04.2018 as part of ticks prevention. The exact dose and administrations way is unknown. Despite the treatment the owner finds ticks on the cats.It is unknown when the owner started to find ticks on the cats. On one cat the owner has found 11 ticks on the cat. The cats has been treated with Frontline previously with good effect. The owner also treated 7 dogs with good effect. |
| 16-May-2018 | UAE; 18SE000087; -; Sweden | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** X<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 20-Apr-2018 | Apr-2018* | 10 Day(s) | D-E | Two cats (1 neutered male and 1 neutered female, 6- 11 years, weight unknown) was treated with Frontline Vet spot-on, batch no R21405AX, on 20.04.2018. The administrations way is unknown. The owner has used Frontline on 2 of 3 cats for many years with good effect, the third cat does not receive treatment as it doesn't get many ticks.<br>This year the 2 treated cats have had much more ticks then previously, and the one without treatment has only had a few . Start date of event is unknown.<br>The customer lives in southern småland, Älmhult, Sweden in a farmer environment with farming land around. |
| 15-May-2018 | UAE; 18SE000096; -; Sweden | **Species:** Feline<br>**Breed:** British Shorthair<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 24-Apr-2018* | 08-May-2018 | 2 Week(s) | D-D | A brief report received y social media :<br>The two British shorthair male cats approximately 4 years old, weight unknown, were treated with Frontline Vet (dose and administrations way unknown). The date of treatment is unknown, so it is chosen by default. Afterward the owner began to find ticks on the cat 1-2 weeks after treatment. The owner has found approximetaly 2 ticks every other day on one of the cats and approximately 5 ticks on the other cat. The last cat is getting ulcers where the ticks has been sitting. |
| 15-May-2018 | UAE; 18SE000098; -; Sweden | **Species:** Canine<br>**Breed:** Schnauzer (Miniature)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 4.00 Year(s)<br>**Weight:** 10 kg* | - | - | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-May-2018 | 03-May-2018* | 2 Day(s) | D-E | Three 4 year old different male dogs of the breed miniature schnauzer, weight 7, 8 and 9 kg respectively was treated with Frontline Comp, spot-on 67 mg/60,3 mg from the same package on the 01-MAY-2018. The owner gave the dogs, her own dog and her sisters two dogs according to the label in the neck and did not shower the dogs. The owner discovered several big ticks which were alive on all three dogs. The owner waited a few days to see if it might take some time to the effect, but every day since the treatment the owner has found ticks. The owner has used Frontline Comp previously where ticks were found but dead, but this time all ticks are alive. |
| 24-May-2018 | UAE; 18SE000105; -; Sweden | **Species:** Feline<br>**Breed:** Domestic Shorthair | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT | 20-Apr-2018 | 20-Apr-2018 | N/A | D-E | A 4-5 years old domestic shorthair neutered male cat, 3.5 kg, was treated with Frontline Vet spot-on, batch no R21614, on 20-APR-2018 and again 18-MAY-2018 as prevention of ticks. |

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| | | (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 3.5 kg | | | | **Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | Despite the treatment the owner found around 10-15 ticks daily on the cat. The owner has treated the cat previously summers where the product had worked fine. |
| 12-Jun-2018 | UAE; 18SE000110; -; Sweden | **Species:** Canine<br>**Breed:** Canine Other<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 6.00 Year(s)<br>**Weight:** 37 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** No (Overdose) | 10-Jun-2018 | 11-Jun-2018* | 1 Day(s) | D-C | The 6 years old male Amstaff dog, 37 kg, was treated with Frontline Comp spot-on on 10.06.2018 as flea and tick prevention. Approximately 1-2 days later the dog began to itch. Due to the itching 4 days later an infected ulcer develops. According to the attending veterinarian the ulcer is infected with streptococs. The dog was clipped and washed and the treatment is continued home with desinfective wash. At the time of reporting the dog had not recovered, however the veterinarian expect that the dog will recovered fully.<br>MAH follow-up comment for clarification: The product used is Frontline Comp spot-on, MAH no 19851, for dogs >40kg. Since the dogs weight is 37 kg, the dose is a overdose. |
| 29-May-2018 | UAE; 18SE000111; -; Sweden | **Species:** Canine<br>**Breed:** Irish Soft-coated wheaten Terrier<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 5.00 Year(s)<br>**Weight:** 14 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 28-May-2018 | 28-May-2018 | 0 Day(s) | D-D | A male Irish Soft coated Wiston Terrier born April-2013, weight 14 kg was treated with Frontline Vet, batch no R21618AX, unknown dose on the 28-MAY-2018 approximately at 8 o'clock as prophylatic treatment against ticks. Approximately two hours later the dog vomits, has diarrhoea and is hyperventilating. The owner called the the veterinarian and the dog was showered and after approximately three hours, the dog was better. The dog has fully recovered.<br>MAH update 27.07.2018: NCA made me awake that we by mistake had chosen the wrong veddra term "Lethargy". Now updated with the right veddra term "Hyperventilation". At the same time change Time to onset from 2 days to 2 hours (a mistake). |
| 25-May-2018 | UAE; 18SE000113; -; Sweden | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | May-2018* | May-2018* | N/A | D-E | A dog of unknown breed, sex, age and weight was treated with Frontline Comp (67mg/60.3 mg) dose and administrationsway unknown, as a prophylactic treatment. The owner contacted the pharmacy and told the pharmacist that this year the product did not had any effect on ticks at all. |
| 15-Jun-2018 | UAE; 18SE000114; -; Sweden | **Species:** Canine<br>**Breed:** Hound Breeds (200 Series)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 20 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used** | 01-May-2018* | 01-May-2018* | 0 Day(s) | D-E | The approximately 3 years old female Wachtel dog, app. 20 kg, was treated with Frontline vet Medium dog (Dose and administration way is unknown) at the beginning of May (The exact date is unknown, so the start date is chosen by default). 1 week after the treatment there was found ticks on the dog and some of them have taken up blood. The dog has been treated with Frontline the previously 2 years with good effect, but this year the effect is poorer. The dog is used for hunting and is often in the forest. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **ok?:** Unknown to Company | | | | | |
| 19-Jun-2018 | UAE; 18SE000119; -; Sweden | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | Jun-2018* | Jun-2018* | 0 Day(s) | D-C | An owner reported on Facebook 19-JUNE-2018 that she had given her female dog, of unknown health status, age and weight, Frontline, product and dose not specified on a unknown date (the product is chosen by default). The dog got ill, changed behaviour (facial expression described as neurological signs) and had diffuculties to stand. The owner washed the dog several times and the next day the dog had improved. The company has contacted the owner for more information, but the owner didn't want to give more information. |
| 19-Jun-2018 | UAE; 18SE000120; -; Sweden | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** - **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 16-Jun-2018 | 19-Jun-2018* | 3 Day(s) | D-D | The cat (breed, gender, age, weight unknown) was treated with Frontline (not specified which product, strength, dose or administrations way) on 16-JUN-2018. Afterward (on at a date between the 16-JUN-2019 and time of reporting 19-JUN-2018) the cat got a ulcer at the application site and according to the owner, the skin has falled of. The cat was attended by a veterinarian, who treated the cat with Cortisone and chlorhexidine washing. The outcome is unknown. |
| 20-Jun-2018 | UAE; 18SE000125; -; Sweden | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | Jun-2018* | Jun-2018* | N/A | D-E | It was reported by owner on social media on the 20-JUN-2018 that her dog of unknown breed, age, sex, weight and health status had been given Frontline by the owners grandfather, product, strength and dose not specified. On an unknown date the dog lost a lot of fur in an unspecified part of the dog. |
| 18-Jun-2018 | UAE; 18SE000128; -; Sweden | **Species:** Canine **Breed:** Boxer **Sex:** F **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** 28 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** Forthyron; **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Apr-2018* | 02-Apr-2018* | 1 Day(s) | D-D | An 8-year old female Boxer of 28 kg was treated with Frontline Spot-on vet, 100 mg/ml, 4 x 2.68 ml in the begining of APRIL-2018 for tick control in the evening at the same time as administration of the product to the cat in the house. The day after approximately 15 hours after administration the owner came home from work and discovered that the dog was salivating. The salivation continued for approximately 4-5 hours and thereafter the dog completely recovered. The dog had hypothyreosis and kidney failure and the dog received Fortyron and special kidney diet, but health status was reported as good. |
| 29-Jun-2018 | UAE; 18SE000133; -; Sweden | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** F **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | Jun-2018* | 23-Jun-2018* | N/A | D-C | A brief report received from a Pharmacy: A 13 years old miniature poodle female dog, 4.9 kg, was treated with Frontline Comp, batch no R62214AL on 20-jun-2018 (dose and administration way unknown). On 22-jun-2018 the dog showed neurological signs (not further described) and got lame on the one |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Neutered<br>**Age:** 13.00 Year(s)<br>**Weight:** 4.9 kg | | | | **Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | front paw, which further developed so the dog vomited, was tired, and had a unstable walk. The dog was washed and got a little better. Approximately 1 week later the dog has not recovered, but the dog has fully recovered on 25.07.2018. The owner don't think that the dog had got any of the product into the mouth. The owner has used Frontline previously on the dog, but not Frontline Comp previously. The dog has not had any side-effect with the other Frontline product (not further specified). |
| 09-Apr-2018 | UAE; 18TW000019; -; Taiwan | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 6 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 09-Apr-2018* | 09-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event in Feline According to the owner, after applying Frontline Plus Cats (Lot number unknown) to her 6 cats, one of them had hair loss and wound. No other information was collected. Reaction start date: unknown |
| 15-Apr-2018 | UAE; 18TW000022; -; Taiwan | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 15-Apr-2018* | 15-Apr-2018* | 0 Day(s) | D-D | Suspected Lack of Efficicay Claim: Patient: Canine; other information unknown As reported by DVM, the owner complained about lack efficacy of fleas/ticks control after using a tube of FRONTLINE PLUS DOG S (lot R60112BX) to his dog. There's no other information collected from the owner. Reaction start date: unknown |
| 23-Apr-2018 | UAE; 18TW000025; -; Taiwan | **Species:** Canine<br>**Breed:** Maltese<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** 3 - 3 kg | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Apr-2018* | 23-Apr-2018 | N/A | D-A | Suspected Adverse Event in Animal Claim: Deceased: Maltese; Female; Intact; 2 years old; 3 kilograms. According to owner, his dog ate a tablet of Heartgard in the morning on 23/04/2018 and no specific finding after that. However, the dog was then found died at noon. The Heartgard tablet was meant to be given on 22/04/2018, but the dog did not eat the tablet, so the teblet was left in the room since 22/04/2018, and the dog ate it on the next morning(23/04/2018). The dog had eaten heartgard a year ago, and no specific finding at that time. Unsure of the heartworm prevention in the past year. The dog was applied with frontline plus recently. |
| 21-May-2018 | UAE; 18TW000033; -; Taiwan | **Species:** Canine<br>**Breed:** Doberman<br>**Sex:** M | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 21-Jan-2018 | 21-May-2018 | 3 Day(s) | D-D | Suspected Adverse Event in Animal Claim: Patient: Doberman Pinscher; Male; 26.5 kilograms; 8 months old As reported by owner, he applied a pipe of frontline plus to his dog and then |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 26.5 kg | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | multiple papules was found at applied area. A month ago, same situation happened but adverse event secondary to vaccination were suspected at that time. (The dog had vaccination and frontline approximately same period of time.) According to owner, this dog was found hypersensitive to specific shampoo ever; before that, owing to lack of definitive diagnosis to hypersensitivity, he kept using frontline monthly until this time. Since there're no other suspected allergen recently, the owner doubted strongly that the papule-like reaction was related to Frontline Plus. Previous applied timing: 1/21, 2/20, 3/20, 4/19 and this time 5/18 |
| 03-Apr-2018 | UAE; 18UK000679; -; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 8 | 8 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 01-Apr-2018* | N/A | D-D | As reported by the animal owner, 8 dogs of unknown age, sex, reproductive status, breed, weight and condition, were administered FRONTLINE SPOT ON DOG (batch, expiry and SKU unknown) via an unknown route by the animal owner on an unknown date at an unknown dose for an unknown indication. The animal owner reports that the product does not appear to work anymore on fleas. They have used the product in the past for many years and found it great. They have not had a flea problem for many years. Though recently they have purchased 2 months doses for the 8 dogs and they are all still loaded with fleas and they still have 8 uncomfortable dogs, all currently scratching away. It seems that the present product has not touched any of the fleas or eggs on their dogs. Start date added for submission purposes only. |
| 03-Apr-2018 | UAE; 18UK000684; Hampshire; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 6.50 Year(s)<br>**Weight:** 9.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Metacam meloxicam 5 mg/ml injection dog cat; Metacam meloxicam 1.5 mg/ml oral suspension dogs; Synulox injection; Synulox tablets;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Others) | 15-Apr-2017 | 17-Apr-2017 | N/A | D-B | As reported by the animal owner, Binkie a 6 year 6 month old, neutered female Crossbreed dog, weighing 9.7 kg and in good health, was given FRONTLINE PLUS SPOT ON DOGS S (batch number: P62013BL and expiry date: AUG 2019) applied by the owner once a year first application on 15 APR 2017 and again on 26 MAR 2018, as a preventative treatment. In both instances the FRONTLINE was applied after grooming (after the animal had been washed, clipped and stripped). On 15 APR 2017 the animal went to the groomers and FRONTLINE was applied, 2 days later on 17 APR 2017 the owner reported that the animal was under the weather, had a high temperature, was lethargic (the animals legs collapsed) and the animal was off its food, and so the animal was taken to the vets. The attending veterinary surgeon reported that the animal was seen and a tick was found on the animal, the animal had a high temperature, was struggling and was lethargic. The animal was given Synulox injection 0.5 ml subcutaneously and a METACAM 5 MG/ML INJECTION FOR DOGS 0.4 ml subcutaneously (dose calculated as 0.2 mg/kg).<br><br>On 18 APR 2017 the animal was re-examined and a blood test was taken for Lymes disease and a health profile. The following medications were dispensed, Synulox tablets 250 mg half a tablet twice a day and METACAM 1.5 mg/ml Oral Suspension , 9.7 kg dose (i.e. 0.1 mg/kg) to be taken orally with food, once a day. The blood tests results revealed that the animal was negative for Borrelia but the animal had neutrophillia and mild ALP increase (value of 117) which was suggestive of an endocrine disease or hyperplasia. The owner also checked with the groomer and a normal shampoo was used and no flea treatment was given. 4 days later on 21 APR 2017 the animal had recovered. On 26 MAR 2018 the animal went to the groomers and FRONTLINE was applied by the owner, an hour later. The owner parted the hair on the back of the shoulders and put the FRONTLINE on the skin, the |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | animal was given a treat afterwards. |
| 06-Apr-2018 | UAE; 18UK000697; -; United Kingdom | **Species:** Canine **Breed:** Bulldog **Sex:** M **Sex qualifier:** Unknown **Age:** 13.00 Month(s) **Weight:** 25.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 02-Apr-2018 | 1 Day(s) | D-D | As reported by the animal owner, Winston a 13 month old, Bulldog, weighing 25.2 kg, and in unknown condition, was given FRONTLINE SPOT ON DOGS L for dogs 20 to 40 kg (batch number and expiry date unknown) on 01 APR 2018 applied to the back of the neck by the owner. The following day on 02 APR 2018 the owner noticed that some of the animal's fur was discoloured. On the evening of the 03 APR 2018 the owner reported that there was quite a nasty smell coming from where they had used the FRONTLINE. The owner called the veterinary surgery on the morning of 04 APR 2018 to make an appointment to see the vet the next day on 05 APR 2018, as the owner was concerned, as the animal also seemed very lethargic. On 05 APR 2018 the discolouration on the animals fur had worsened, along with the smell, the animal had also completely gone off food and water. The attending veterinary surgeon gave the animal two antibiotic injections, the owner was told that the animal had a severe infection which very much resembled a burn to the skin. The owner made a follow up appointment for 06 APR 2018, to see what impact the antibiotics had made. On 09 Apr 2018 the animal owner provided invoices which depict treatment administered to the animal. This treatment included, on 05 APR 2018, Baytril Injection 2.5 percent per ml and METACAM injectable (assumed METACAM 5 MG/ML SOLUTION FOR INJECTION), and on 06 APR 2018 Baytril 50 mg tablets and METACAM ORAL SUSPENSION (assumed METACAM 1.5 MG/ML ORAL SUSPENSION). The attending vet reported that on 05 APR 2018 the animal presented with wet dermatitis and on 06 APR 2018 when the animal came in for a recheck, there was an improvement. On 12 APR 2018 the attending vet reported that the animal was getting back to itself and the reaction was clearing up. On 20 APR 2018 the animal owner reported that all seems well, the animal is due back to the vet for a routine follow up today, and the vet or pet owner will update if any outcome other than resolution. No |
| 09-Apr-2018 | UAE; 18UK000713; -; United Kingdom | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-Apr-2018* | N/A | D-D | As reported by the animal owner, a female yorkshire Terrier of unknown age, reproductive status weight and condition, was adminstered FRONTLINE PLUS SPOT ON DOG (assumed S) (batch and expiry unknown) via an unknown route to an unknown site by the animal owner on an unknown date for an unknown indication. The animal owner reported that the animal has been on FRONTLINE PLUS for quite a while, but now just recently, when it says you should apply every 8 weeks, after a month she has started scratching and the owner wonders if you can give it to them more frequently. Start date of event added for submission purposes only. |
| 11-Apr-2018 | UAE; 18UK000726; Surrey; United Kingdom | **Species:** Feline **Breed:** European **Sex:** F **Sex qualifier:** Neutered **Age:** 1.83 Year(s) **Weight:** 3.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products | N/A | 10-Mar-2018 | 0 Day(s) | D-E | Suspected lack of efficacy. Owner bought to treat fleas seen on cat. Fleas still present now. Unknown how long they waited before reporting the lack of efficacy. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | | | | | |
| 13-Apr-2018 | UAE; 18UK000746; Cheshire; United Kingdom | **Species:** Canine **Breed:** Schnauzer (Miniature) **Sex:** M **Sex qualifier:** - **Age:** 3.00 Month(s) **Weight:** 4.95 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Metacam meloxicam 2 mg/ml solution for injection cats; Nisamox; Dexafort; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose) | 29-Mar-2018 | 30-Mar-2018 | 1 Day(s) | D-C | As reported by the animal owner, Bennie an 18 week old, intact male Miniature Schnauzer dog, weighing 4.95 kg and of good health, was given FRONTLINE PLUS SPOT ON DOGS M (batch number and expiry date unknown) for 10 – 20 kg dogs applied topically on 29 MAR 2018, administered by the animals owner, as a flea treatment. The owner believed that the retail outlet picked the wrong strength flea treatment, as the owner remembered there being a golden dog on the front of the packet which is for 10 – 20 kg dogs (not the 2 – 10 kg FRONTLINE PLUS SPOT ON DOGS S, which the owners dog would need). The attending vet reported that on 30 MAR 2018 the day after applying the FRONTLINE PLUS SPOT ON DOGS M the animal was lethargic, but was eating and drinking normally, it was thought that it was unlikely that the FRONTLINE had been licked off. On 03 APR 2018 (5 days after the FRONTLINE application) the first time the attending vet had examined the animal. No diarrhoea or vomiting had been reported but the animal was very lethargic and going off back legs . On examination, the animal was not dehydrated, the abdomen was soft, the skin looked ok, mucous were pink, the heart and chest were clear, the trachea was reactive, submandibular lymph nodes were slightly enlarged, the animals temperature was 38.9C and no abnormalities were detected in the abdomen, no coughing was seen, but a few sneezes, the animal was scratching its neck, the assessment made was that the animal had a possible upper respiratory tract infection, if the animal was no better in 24-48 hours further tests would be carried out. The animal was given the following treatment a Dexafort injection 0.5 ml and Nisamox tablets. On 08 APR 2018 the owner reported that the animal was no better, the animal was eating, drinking and passing urine and faeces as normal but was still off their legs and was very lethargic, the antibiotics had not helped. On 09 APR 2018 the animal was admitted, the animal had breakfast at 6am was still |
| 16-Apr-2018 | UAE; 18UK000761; -; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 09-Apr-2018* | 0 Day(s) | D-D | As reported by the animal owner, a canine of unknown age, sex, reproductive status, breed, weight and condition, was administered FRONTLINE PLUS DOG M (assumed FRONTLINE PLUS SPOT ON DOG M) (batch R60906AR, expiry unknown) via an unknown route to an unknown site by an unknown administrator 1 week ago (estimated as 09 APR 2018) for an unknown indication. The animal owner reports that they bought the product online, have used it many times before but this is from a different source . They applied the product a week ago and the animal has been scratching more after application than before. The animal owner wanted reassurance that they had a genuine product. The batch number has been checked and is a recognised batch. |
| 19-Apr-2018 | UAE; 18UK000790; South Yorkshire; United Kingdom | **Species:** Canine **Breed:** Pointer **Sex:** M **Sex qualifier:** Neutered | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other | 14-Apr-2018 | 14-Apr-2018 | 0 Day(s) | D-C | As reported by the attending veterinary surgeon, Roly, an 18 month old male neutered Cypriot Pointer canine weighing 15 kg and in good condition was administered FRONTLINE SPOT ON DOG (assumed FRONTLINE SPOT ON DOG M, batch R21616, expiry 30 SEP 2020) topically to an unknown site by the animal owner at |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Age:** 1.50 Year(s)<br>**Weight:** 15 kg | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | a dose of 1 pipette (1 dosage form) on 14 APR 2018 for an unknown indication. It is reported that the animal was imported from Cyprus last year and has sketchy history, the animal owner thinks that the animal has had Leishmania, but the attending vet thinks that the animal had Ehrlicia canis previously. The attending vet reports that an hour after having the FRONTLINE the animal showed symptoms of organophosphate poisoning including twitching, ataxia, hypersalivation and high temperature. The animal saw the vet out of hours and was admitted for IV Fluid therapy, Diazepam and Atropine. This carried on for 12 hours and then did recover, the animal was reported as quite bad but has since made a full recovery. |
| 19-Apr-2018 | UAE; 18UK000791; Kent; United Kingdom | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 26-Dec-2017* | approximately 2 Day(s) | D-D | As reported by the animal owner, Binks, a male neutered Domestic Shorthaired feline of unknown age, weight and condition, was administered FRONTLINE SPOT ON CAT (batch and expiry unknown) topically to the back of the neck by the animal owner just before Christmas (estimated as 24 DEC 2017) at a dose of 1 pipette (1 dosage form) as parasite control. The animal owner reports that they have been using the product for ages, given at the time that is says and most recently was a while ago, just before Christmas, when the owner stopped using the product. The animal owner reports that the animal has an allergy to fleas. Within 2 days of application (estimated as 26 DEC 2017) the animal was scratching like mad and the animal also had application site fur loss. It is also reported that when the animal was on FRONTLINE, he took 30 fleas off. The animal owner reports that for the last few months they have been just brushing the animal and the fleas out. Today, 19 APR 2018, the animal owner took the animal to the vets and they gave another product. No sprays or any other environmental treatment have been used, however it is reported that the house is hoovered and washed regularly. |
| 25-Apr-2018 | UAE; 18UK000833; -; United Kingdom | **Species:** Canine<br>**Breed:** Pyrenean Mountain Dog<br>**Sex:** F<br>**Sex qualifier:** Not applicable<br>**Age:** 7.00 Year(s)<br>**Weight:** 57 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Metacam meloxicam 1.5 mg/ml oral suspension dogs; Pardale;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Mar-2018 | 21-Apr-2018 | 1 Day(s) | D-B | As reported by the animal owner, Willow a 7 year old female entire Pyrenean Mountain Dog weighing 58.3 kg and in good condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOGS XL, batch R60905AR, expiry 31 MAR 2020) topically to the back of the neck by the animal owner at a dose of 1 dosage form per month from 20 MAR 2018 to 20 APR 2018 for parasite control. The animal also received METACAM (assumed METACAM 1.5 MG/ML ORAL SUSPENSION (batch and expiry unknown) via an unknown route to an unknown site by an unknown administrator at a 55 kg (0.09 mg/kg) dose on 12 APR 2018 for lameness. On 17 APR 2018 the animal was seen for a review of the lameness, was still a little bit sore and so the attending vet dispensed a seven day course of Pardale 400 mg tablets, 3 tablets every 8 hours (assumed administered). The animal owner reports that on Friday 20 APR 2018, they broke the FRONTLINE capsule open and applied it to the back of the animal's neck like they always have done, by parting the fur and putting it on the skin. The animal seemed quiet over the weekend (21 and 22 APR 2018), the owner didn't know the cause. On Monday 23 APR 2018, about 3:30 pm they had taken the animal out for a walk and everything seemed ok. The animal got up suddenly and went to the door so the owner opened it and let the animal out. The animal vomited immediately, no heaving like dogs normally do, literally just threw up. The animal stood there with the head down, eyes scrunched up, swaying. The animal owner put their hand on the animal and she was trembling, then the animal |

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| | | | | | | | | | | | started stretching her head up, described it as 'looking at the stars', the animal owner said that the attending vet said it was like a seizure. They went straight to the vets. The animal was checked over and temperature was taken, and blood results would be sent to the owner. They took the animal back home, no medication was given as it was a one-off. When they came home the animal went to lay out in |
| 24-Apr-2018 | UAE; 18UK000846; Berkshire; United Kingdom | **Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** Unknown | 1 | 1 | 1 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Apr-2006* | 01-Apr-2011* | N/A | D-A | As reported by the animal owner, Amber, an approximately 14 year old female neutered Labrador Retriever canine, of unknown weight and condition was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG L) (batch and expiry unknown) via an unknown route by an unknown administrator at an unknown dose for an unknown indication. It is reported that a few years ago (about 7) the animal owner had two dogs that were both treated with FRONTLINE. The FRONTLINE was used for the last 5 years of the animal's lives. One animal, Amber, would always seem hot and pant for 48 hours after application. The animal owner reports that the animal was a delicate dog and things affected her differently. It is reported that the animals were 14 years old when they died (details unknown). Start date of adverse event added for submission purposes only. |
| 24-Apr-2018 | UAE; 18UK000847; Berkshire; United Kingdom | **Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** Unknown | 1 | 1 | 1 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Apr-2006* | 01-Apr-2011* | 7 Year(s) | D-A | As reported by the animal owner, Gale, an approximately 14 year old female neutered Labrador Retriever dog, of unknown weight and condition was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG L, batch and expiry unknown) via an unknown route by an unknown administrator at an unknown dose for an unknown indication. It is reported that a few years ago (about 7) the animal owner had two dogs that were both treated with FRONTLINE. The FRONTLINE was used for the last 5 years of the animal's lives. The animal owner reports that Gale was previously a Guide Dog and took her retirement to heart, was terrible at walking on the lead and was't good at remembering things. It is reported that the animals were 14 years old when they died (details unknown). Start date of adverse event added for submission purposes only. |
| 27-Apr-2018 | UAE; 18UK000858; -; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-Apr-2018* | N/A | D-D | As reported by the animals owner, a female dog, of unknown breed, age, weight and reproductive status, was given FRONTLINE (assumed to be FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, route, frequency and date of administration unknown, administered by unknown. Following use, the owner reported that the animals skin had become much darker almost black in parts, which was mainly on the animals legs and stomach, apart from this the dose did not seem to bother the animal. No further information was provided. Start date of adverse event added for submission purposes only. |
| 02-May-2018 | UAE; 18UK000879; -; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown | N/A | 01-Mar-2018* | N/A | D-E | As reported by the animal owner, Stella, a canine of unknown age, sex, reproductive status, weight and condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOGS M, batch and expiry unknown) via an unknown route to an unknown site by the animal owner at a dose of 1 dosage form every 8 weeks for an unknown indication. The animal owner reported that they have converted from FRONTLINE to FRONTLINE PLUS in recent months. They have always used FRONTLINE on their animal and the animal has never had fleas. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **Was the product used ok?:** Yes | | | | | Stella is the only animal in the house. The animal owner says that they have never let the treatment lapse and the animal does not swim, but that the animal now has fleas (reported to start MAR 2018, estimated as 01 MAR 2018) and the animal owner is combing the animal regularly. The animal owner reports that they are being bitten and have treated the house with Virbac Indorex 4 weeks ago. |
| 03-May-2018 | UAE; 18UK000893; -; United Kingdom | **Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 24.000 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-May-2018* | N/A | D-D | As reported by the animal owner, Ozzy, an approximately 5 year old male Labrador weighing approximately 24 kg, was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG L, batch and expiry unknown) via an unknown route to an unknown site by the animal owner at an unknown dose on an unknown date for an unknown indication. The animal owner reported that they recently got the animal as a rescue, and that all of their previous dogs and had no issues. The animal owner reported that Ozzy appears to get very uncomfortable after the animal owner first applies the product, so much so that they had to put the animal in the shower and wash him. Start date added for submission purposes only. |
| 30-Apr-2018 | UAE; 18UK000896; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 30-Jan-2018* | 30-Apr-2018* | 0 Day(s) | D-D | As reported by the animal owner, two young felines, of unknown age, sex, reproductive status, weight and condition, were administered FRONTLINE PLUS SPOT ON CATS (batch and expiry unknown) via an unknown route at an unknown site by the animal owner from an unknown date (estimated as 30 JAN 2018) to prevent any flea infestation. The animal owner reports that they have (so they thought) fastidiously been treating the animals. They recently bought two 6 packs of the product and have just come to the end of the first pack (estimated as approximately 3 months treatment). The animal owner reports however that they now (estimated as 30 APR 2018) find themself in a position where they have a flea/egg problem within the house and feel that this product has been useless in preventing and treating this. |
| 01-May-2018 | UAE; 18UK000897; -; United Kingdom | **Species:** Canine **Breed:** Collie **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-May-2018* | N/A | D-E | As reported by the animal owner, approximately 2 Rough Collies, of unknown age, sex, reproductive status, weight and condition, were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG L, batch and expiry unknown) via an unknown route to an unknown site by an unknown administrator at an unknown dose from an unknown date for an unknown indication. The animal owner reports that the product doesn't work on her animals any more, that the fleas or immune or that an ingredient has been taken out. Start date added for submission purposes only. |
| 02-May-2018 | UAE; 18UK000901; Billinge, Wigan; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-May-2018* | N/A | D-E | As reported by the animal owner, a small breed canine of unknown age, sex, reproductive status, breed, weight and condition, was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown) via an unknown route to an unknown site by the animal owner at an unknown dose on an unknown date as a parasiticide. The animal owner reports that they found a tick on the animal and removed it. They then treated with FRONTLINE. They found another a day later but when they removed it, it was still alive. The animal owner reports that the tick that was alive was on the animal for 72 hours but was still alive when removed. Start date of event added for submission purposes only. |

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| 05-May-2018 | UAE; 18UK000910; Somerset; United Kingdom | **Species:** -<br>**Breed:** -<br>**Sex:** -<br>**Sex qualifier:** -<br>**Age:** -<br>**Weight:** - | - | - | - | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** -<br>**Was the product used ok?:** - | N/A | N/A | N/A | D-E | As reported by the animal owner, they purchased FRONTLINE PLIS SPOT ON CATS (batch P40701AL, expiry 01 APR 2019) and once they peeled back the interior plastic packaging, they noticed that the inside was damp. The snap back to release part was not fully intact, allowing the dispensers to leak into the plastic interior package. This was the case for two of the six pack purchased. |
| 08-May-2018 | UAE; 18UK000911; -; United Kingdom | **Species:** Feline<br>**Breed:** Domestic Longhair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** 2.9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 25-Apr-2018* | N/A | D-D | As reported by the animal owner, Princess, a female neutered Domestic Longhaired feline of unknown age, weighing 2.9 kg and in unknown condition, was administered FRONTLINE SPOT ON CAT (batch P20713, expiry JAN 2019) via an unknown route to an unknown site by the animal owner at an unknown dose every four weeks on an unknown date as parasite control. The animal owner reports that they have always used FRONTLINE for their cat but they had to take the animal to the vet. They report that all the fur was coming out at the back and also the tail and the legs. The animal owner reports that the attending vet thinks that it was caused by fleas. The veterinary clinic staff member reported that they have not prescribed FRONTLINE from there before. The animal was seen by the vet for the first time on 25 APR 2018 and the animal was full of scabs, over the spine and neck with self inflicted alopecia on the lumbar spine. The animal given a Depomedrone injection - 0.36 ml and some Indorex house spray. Start date estimated for submission purposes only. |
| 05-May-2018 | UAE; 18UK000921; -; United Kingdom | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 01-May-2018 | N/A | D-D | As reported by the animal owner via social media, a cat of unknown age, sex, breed, and weight, was given FRONTLINE (assumed to be FRONTLINE SPOT ON CAT, batch number and expiry date unknown) on an unknown date, administered by unknown, and experienced a bald patch where the product had been applied. Start date of adverse event added for submission purposes only. |
| 06-May-2018 | UAE; 18UK000930; -; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 06-May-2018* | 2 Week(s) | D-E | As reported by the animal owner, a canine of unknown age, sex, reproductive status, breed, weight and condition, was administered FRONTLINE Plus for Dogs (assumed FRONTLINE PLUS SPOT ON DOGS M, batch and expiry unknown) via an unknown route by an unknown administrator at an unknown dose on an unknown date for an unknown indication. The animal owner reports that the animal was carefully weighed before purchasing to ensure the correct dosage and that the instructions were followed very carefully, but nearly two weeks later they have noticed that their animal is still carrying fleas. They report that the product has not worked for their animal at all. |

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| 10-May-2018 | UAE; 18UK000933; -; United Kingdom | **Species:** Canine **Breed:** West Highland White **Sex:** U **Sex qualifier:** Unknown **Age:** 14.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 10-Apr-2018* | N/A | D-D | As reported by the animal owner, a 14 year old West Highland White terrier canine of unknown sex, reproductive status, weight and condition, was administered FRONTLINE Spot On (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) via an unknown route by the animal owner at an unknown dose on an unknown date for an unknown indication. The animal owner reports that the product has always been brilliant with fleas and that they had never had any problems with ticks until recently. The animal owner reports that recently, about a month ago (estimated as 10 APR 2018), they have got some active ticks off the animal. The attending vet suggested that the FRONTLINE might not be working and advised that they use a Seresto collar. However the animal owner reports that they want to continue using the FRONTLINE, the animal is very old and they don't want to be changing things. |
| 09-May-2018 | UAE; 18UK000937; Cambridgeshire; United Kingdom | **Species:** Canine **Breed:** German Shepherd Dog **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 01-Mar-2018* | N/A | D-D | As reported by the animal owner, Savannah, a German Shepherd Dog of unknown sex, weight and condition, and two other canines of unknown age, sex, reproductive status, breed weight and condition, were administered FRONTLINE Plus (assumed FRONTLINE PLUS SPOT ON DOGS M, batch and expiry unknown) topically to an unknown site by the animal owner at an unknown dose on an unknown date for an unknown indication. The animal owner reports that FRONTLINE PLUS is no longer working on their dogs. They report that they have treated the home and their pets three times now and it has not worked. The animal owner reports that they are seeing fleas on one of the dogs, Savannah. They had to take this animal to the vet, who said that the fleas were under the animal's skin, and had to pay for Steroids despite a high dose of FRONTLINE. The animal owner reports that the animals are bathed once a month before the flea treatment but not after, and that Savannah does not go out and isn't socialised as they want the animal to be a guard dog. The animal owner reports that they are not being bitten themself, and that they have used Bob Martin Home Spray every two weeks and steam cleaned the house. Start date of event added for submission purposes only. |
| 10-May-2018 | UAE; 18UK000943; Moray; United Kingdom | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 5.4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 09-May-2017* | 09-May-2017* | 0 days | D-B | As reported by the attending veterinary surgeon, Girlie Lee, an approximately 10 year old female neutered Domestic Shorthaired feline weighing 5.4 kg and in good condition was administered FRONTLINE COMBO SPOT ON CAT (batch and expiry unknown) topically to the back of the neck by the animal owner at a dose of 1 dosage form a year ago (estimated as 09 MAY 2017) as routine flea control. It is reported that an unknown amount of time following administration the animal had a seizure. The animal owner administered the same product FRONTLINE COMBO SPOT ON CAT (batch and expiry unknown) topically to the back of the neck at a dose of 1 dosage form on 09 MAY 2018 and the animal has had another few seizures. The product was dispensed as a single pipette and the animal owner applied it on the Wednesday evening, shortly afterwards the animal had a seizure and then another in the early morning - the animal was trembling, salivating and ear twitching. The animal was presented to the attending vet yesterday 09 MAY 2018, and the animal was still ear twitching. The animal's blood results were normal, but the animal was kept in hospital for observation and had another two seizures overnight. The animal owner reported that it was the same thing that happened approximately a year ago, they report that it was a green packet which they believe was also FRONTLINE COMBO however |

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| | | | | | | | | | | | this was not dispensed from the attending vet and so this is not confirmed. The animal owner did confirm that they applied the product to the back of the neck and do not think that the animal licked the product off. It is reported that the animal has had BROADLINE in the past - 06 MAR 2017 and 5 DEC 2017 - and had no problems with that. |
| 13-May-2018 | UAE; 18UK000954; -; United Kingdom | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 16.00 Year(s) **Weight:** 4.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2002* | 09-May-2018 | 2 Day(s) | D-D | As reported by the animal owner, Sassy a 16 year old male neutered Domestic Shorthaired feline weighing 4.2 kg and in good condition, was administered FRONTLINE SPOT ON CAT (batch and expiry unknown) topically by the animal owner at a dose of 1 pipette on 07 MAY 2018 as a parasiticide. It is reported that 2 days later a small bit of hair loss appeared. The animal owner reported that they thought that he had been fighting, and that by Thursday (10 MAY 2018) the animal was bald in that area. The skin at the reaction site is normal and there is no irritation or soreness. The animal is going to go to the vets for a check up, as the animal owner reports that it is unusual that the animal has reacted now when it has had FRONTLINE for 16 years (since he was a kitten). The animal owner said that the vet has suggested that it may be due to something underlying as the animal is aging. |
| 15-May-2018 | UAE; 18UK000970; East Riding of Yorkshire; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 01-May-2018* | N/A | D-E | As reported by the animal owner, a feline of unknown age, breed, sex, reproductive status, weight and condition, was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) topically by the animal owner at a dose of 1 dosage form on an unknown date for an unknown indication. The animal owner reports that the product is not working and is adamant that the animal has been treated regularly. The animal owner reports that when they got the animal, he was treated with something at the vets that was apparently very expensive but worked. It is reported that they haven't missed a month of treatment, and it is reported that the animal owner's wife and daughter are being very badly bitten. The animal owner reports that they won't be using FRONTLINE anymore and will have to go to the vets and get the stuff that is much stronger and actually works . Start date added for submission purposes only. |
| 16-May-2018 | UAE; 18UK000973; Shropshire; United Kingdom | **Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 29.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 15-May-2018 | 6 Day(s) | D-C | As reported by the animal owner, Molly, a female neutered Labradoodle (labrador cross poodle) canine, born 04 NOV 2015, weighing 29.1 kg and in good condition, was administered FRONTLINE SPOT ON DOG L (batch P20904AA, expiry JUL 2019) topically by the animal owner at a dose of 1 pipette one week ago (estimated 09 MAY 2018) as preventative care. The animal owner reports that they have used the before when the animal was a puppy, increasing the dose as the animal got heavier. Other times, the animal has just got drowsy on the days that they've given it to her, hence they usually do it at an evening time. The animal is reportedly never drowsy enough to make her lethargic (reported in case 18UK001138). However, this time the dog didn't really have any of those reactions but the animal owner has noticed that it is a week after and the animal has got this lump which is like the size of a small fist, it isn't like a 10 pence, it's probably a couple of inches in diameter. The animal owner reports that they noticed the lump under the skin where they applied the product on 15 MAY 2018. On 17 MAY 2018 the animal owner reported that they had taken the animal to the vets where they had taken a swab for testing. On 18 MAY 2018 the attending vet reported that 8 days after the FRONTLINE application the owner |

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| | | | | | | | | | | | noticed the lump on the animals back. The animal was examined by the vet on 17 MAY 2018 and was reported to be in excellent condition, the owner reported that the animal had been eating, drinking, urinating and defaecating normally and had no particular concerns. The attending vet found a subcutaneous mass between the shoulder blades of the animal, 3cm x 1.5 cm thick, it was attached to the skin but not to the underlying tissue, the skin was perfectly normal on top of it. No pain or scratching was elicited although the animal did start to react a bit after the lump was manipulated for a while. A fine needle aspiration of the lump was performed. The attending vets opinion was |
| 27-Apr-2018 | UAE; 18UK001005; -; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 27-Apr-2018 | 3 Day(s) | D-E | As reported by the animal owner, a canine, of unknown age, breed, sex and reproductive status, weighing 9 kg and in unknown condition, was administered FRONTLINE SPOT ON DOG S (batch and expiry unknown) via an unknown route to an unknown site by the animal owner at an unknown dose three days ago (estimated to be 24 APR 2018) as they found a small brown tick on their animal. It is reported that they applied the treatment, but at the time of reporting the tick had swelled and showed no sign of falling off . Further details are not known. |
| 15-May-2018 | UAE; 18UK001006; -; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 01-May-2018 | N/A | D-E | As reported by the animal owner, a female dog, of unknown breed, age, weight and reproductive status, was given FRONTLINE PLUS made for large dogs (assumed to be FRONTLINE PLUS SPOT ON DOGS L), batch number and expiry date unknown, applied topically by the owner, frequency and date of administration unknown and the animal still ended up getting fleas, the owner also found a tick. A further pipette was applied about 3 weeks later and the owner was still finding a number of fleas and ticks on the animal. No further information was provided. Start date of adverse event 01 MAY 2018 added for submission purposes only. |
| 22-May-2018 | UAE; 18UK001028; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-May-2018* | N/A | D-E | As reported by the animal owner, two felines of unknown age, sex, reproductive status, breed, weight and condition, were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown) via an unknown route to an unknown site by an unknown administrator at an unknown dose on an unknown date for an unknown indication. The animal owner reports that they purchased this product for both their cats and that it hasn't worked at all. Start date added for submission purposes only. |
| 22-May-2018 | UAE; 18UK001032; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 1 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the** | N/A | 01-May-2018 | N/A | D-A | As reported by animal owner, a female cat of unknown name, age , weight, breed and reproductive status, was given FRONTLINE (assumed to be FRONTLINE SPOT ON CAT, batch number and expiry date unknown) from an unknown date, administered by the animal owner, as a regular flea treatment and the animal had fleas close to the skin, which was discovered by the attending vet when the animal was inspected for an unspecified illness. The animal was then put down on 22 MAY 2018, as a tumour was found. No |

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| | | | | | | **product used ok?:** Unknown to Company | | | | | further information was available. Start date of event entered as 01 MAY 2018 for submission purposes. |
| 23-May-2018 | UAE; 18UK001033; -; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-May-2018 | N/A | D-D | As reported by the animal owner, a male canine of unknown age, breed, reproductive status , weight and condition, was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG L, batch and expiry unknown) via an unknown route to an unknown site by the animal owner at an unknown dose on an unknown date for an unknown indication. The animal owner reports that they bought the treatment online and that it has burned and blistered the animal's skin. They report that they have had no problems before with other flea treatment products. Start date of event added for submission purposes only. |
| 23-May-2018 | UAE; 18UK001039; -; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 09-May-2018* | 0 Day(s) | D-E | As reported by the animal owner, a dog of unknown breed, age, weight, condition and reproductive status received FRONTLINE PLUS SPOT ON DOGS (assumed L, batch number P62013AL, expiry unknown), administered by the animal owner at an unknown dose, via an unknown route on approximately 09 MAY 2018 for treatment of fleas. On 23 MAY 2018 the animal owner reported that two weeks ago they gave the dog an application of FRONTLINE PLUS, batch no P62013AL, it didn't work. No further information was provided. |
| 25-May-2018 | UAE; 18UK001053; -; United Kingdom | **Species:** Canine **Breed:** Spaniel **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 18 kg* | 4 | 4 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 11-May-2018 | 25-May-2018* | 2 weeks | D-E | As reported by the animal owner, 4 Spaniel dogs, of unknown age and reproductive status, weighing approximately 18 kg received FRONTLINE PLUS SPOT ON DOGS M, for dogs 10-20 kg, batch number and expiry date unknown, applied topically, on 11 MAY 2018, administered by the animal's owner, as a pesticide, as the animals had fleas prior to treatment. The owner reported that 2 weeks later on the 25 MAY 2018, the animals still have fleas, the mother had 15 fleas (this animal lived indoors) and the other 3 animals lived outdoors. The owner reported that spray had been used in the house and in the animal's kennels and bedding. The owner reported that another flea spray had been used on the mother since using FRONTLINE PLUS. No further information was provided.<br>UPDATE 17 JUL 2018: Following internal review product problem type changed to SLOE. |
| 25-May-2018 | UAE; 18UK001056; Midlothian; United Kingdom | **Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** 10 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 25-May-2018* | N/A | D-E | As reported by the attending vet, Molly, a neutered female cocker spaniel dog, weighing approximately 10 kg, of unknown age, and of unknown health, was given FRONTLINE SPOT ON (assumed to be FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, route unknown, on 20 MAY 2018, administered by the animal's owner as a parasiticide, as the owner reported that the animal was covered in ticks after being up North. However after applying the FRONTLINE the owner reported on 25 MAY 2018 that the ticks were still there and new ones were appearing. The attending vet had not seen the animal, but the animal was due in that day, the attending vet was intending to use NEXGARD SPECTRA that day. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 25-May-2018 | UAE; 18UK001060; -; United Kingdom | **Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** - **Age:** 8.00 Week(s) **Weight:** 2.68 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 25-May-2018 | 25-May-2018 | 0 Day(s) | D-D | As reported by the attending veterinary surgeon, Simba an 8 week old, intact male golden Labradoodle dog, weighing 2.68 kg and of good health, was given FRONTLINE PLUS SPOT ON DOGS S (batch number: R61422 and expiry date: JUN 2020) applied topically on 25 MAY 2018 once only, applied by a member of the shop floor team, as a parasiticide. The puppy went home and slept for 1 hour then woke up and vomited bile twice in 5 minutes. The animal was seen at the vets the clinical examination was normal, the animal was urinating normally and had eaten some treats. No further details are expected. |
| 25-May-2018 | UAE; 18UK001061; -; United Kingdom | **Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 9.5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 25-May-2018 | N/A | D-E | As reported by the animals owner, Rufus, an Australian miniature labradoodle dog of unknown age and reproductive status, weighing 9.5 kg and of unknown health, was given a single pipette of FRONTLINE PLUS (assumed to be FRONTLINE PLUS SPOT ON DOGS S) batch number and expiry date unknown, a few weeks previously (date unknown), administered by the animals owner and on 25 MAY 2018 the owner reported that the animal had a tiny tick on the rim of the animals eyelid, too small to go at with the tool and the owner was reluctant to jab the tick with tweezers. The owner reported that they tended to walk in forests so ticks were a common problem. Generally the ticks made for the animals eye area where there is naked skin (as the animals coat was dense and woolly and checked after each walk). |
| 27-May-2018 | UAE; 18UK001062; -; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-May-2018* | N/A | D-D | As reported by the animals owner, a female dog, of unknown breed, age, weight and reproductive status, was given FRONTLINE (assumed to be FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, route, frequency and date of administration unknown, administered by the owner after the animal had been to the groomers. After an unknown time the owner reported that the animal was itching, the owner thought the animal may be allergic to the shampoo that had been used by the groomers so bathed the animal in a sensitive shampoo, but then the owner saw at least 4 fleas wash off the animal. The owner reported that they also had a cat who is not itching and none of the human family had had any bites at all, the animals bedding had also been washed, so the owner thought that the animal was not getting re-infected. No further information was provided. Start date of adverse event 27 MAY 2018 added for submission purposes only. |
| 27-May-2018 | UAE; 18UK001063; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown | 25-May-2018* | 27-May-2018* | 2 Day(s) | D-E | As reported by the animals owner, their cats (assumed 2 cats), of unknown age, sex, weight and reproductive status, were given FRONTLINE PLUS SPOT ON CATS, (batch number and expiry date unknown) via an unknown route on assumed date 25 MAY 2018, administered by the owner, along with treating the home with staykill home spray. The owner reported that 2 days later on 27 MAY 2018 they had not seen a single dead flea they were all very much alive and kicking, the owner was seeing them everywhere and they were already doing everything possible to get rid of them. The owner also reports having a 17 month old son who is also being bitten. No further information was provided. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 27-May-2018 | UAE; 18UK001064; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 27-May-2018 | 1 Day(s) | D-E | As reported by the animals owner, their cats (assumed 2 cats), of unknown age, sex, weight and reproductive status, were treated with FRONTLINE (assumed to be FRONTLINE SPOT ON CAT), on 26 MAY 2018, batch number and expiry date unknown, the owner applied it correctly on the cats skin hair parted in between should blades like they have done for years, the whole house had also been treated and the animals still have fleas on 27 MAY 2018. No further information was provided. |
| 29-May-2018 | UAE; 18UK001066; -; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 30-Apr-2018* | 30-Apr-2018* | N/A | D-D | As reported by retail outlet employee on 29 MAY 2018, an animal owner, had bought a 6 Pack of FRONTLINE SPOT ON DOG L (20-40kg) from the store in late APR 2018 and since using the product (assumed to have started to use the product on 30 APR 2018) on their male cat of unknown age, breed, weight and reproductive status, the owner had noticed a lot of ticks on the dog and the owner had had to take the dog to the vets a couple of times. No further information was provided. Start date added for submission purposes only. |
| 31-May-2018 | UAE; 18UK001075; -; United Kingdom | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Unknown **Age:** 8.00 Month(s) **Weight:** Unknown | 2 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-May-2018* | N/A | D-D | As reported by the animal owner, two male Shih Tzu canines, of unknown reproductive status, one 5 years old and one 8 months old, of unknown weights and condition, were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) via an unknown route to an unknown site at an unknown dose by an unknown administrator on an unknown date for an unknown indication. The animal owner reports that the FRONTLINE works well on the five year old dog, but that the problem is with the 8 month old. Ever since they got the animal at 11 weeks, it has been treated regularly with the correct dose of FRONTLINE, but every time, within a couple of weeks, they notice fleas on him and the animal itches a lot. The animal is groomed regularly and bathed once a month before treatment but it still happens. This is only happening with the puppy, and as a precaution the animal owner bought house spray and did the whole home just in case. The animal owner reports that there are two cats that live next door and that the puppy likes to run around the garden. Start date of event added for submission purposes only. |
| 30-May-2018 | UAE; 18UK001080; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 30-Dec-2017* | N/A | D-D | As reported by the animal owner via Social Media, two indoor cats of unknown age, sex, reproductive status, breed, weight and condition, were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown) via an unknown route, to an unknown site, by an unknown administrator at an unknown dose on an unknown date for an unknown indication. The animal owner reports that the product does not work, that they struggled for over six months and it did not kill the fleas on their indoor cats. Start date added for submission purposes only. |
| 30-May-2018 | UAE; 18UK001082; | **Species:** Feline **Breed:** Feline | 2 | 2 | 0 | **Product used:** FIPRONIL | N/A | 01-May-2018* | N/A | D-D | As reported by the animal owner via email and Social Media, two felines of unknown age, sex, reproductive status, breed, weight |

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| | -; United Kingdom | (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | and condition, were administered FRONTLINE PLUS SPOT ON CATS (batch and expiry unknown) via an unknown route, to an unknown site, by the animal owner at a dose of 1 vial every 4 weeks from an unknown date as a preventative treatment. The animal owner reports that they do it every four weeks, and even write it down to remind themself to do it. They have always used it, but more recently it's not working. They have got loads of fleas when the animal owner combs them with a flea comb. They are outdoor cats, but only go into the garden and there is no wildlife or other animals visiting the area - though they agreed that there could be wildlife at night - foxes, hedgehogs etc. The animal owner reports that they have also been using a household spray from the chemist, but that there had got to be at least 10 on each cat when they brushed them today. The animal owner reports that they are being bitten around their ankles. The animal owner reports that even though they used it only a few days ago, they just combed their cats and they had loads of live fleas. Start date added for submission purposes only. |
| 30-May-2018 | UAE; 18UK001083; -; United Kingdom | **Species:** Canine<br>**Breed:** Collie<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 01-May-2018* | N/A | D-D | As reported by the animal owner via social media, two Collie canines of unknown age, sex, reproductive status, weight and condition, were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG , batch and expiry unknown) via an unknown route, to an unknown site, by an unknown administrator at an unknown dose, on an unknown date for an unknown indication. The animal owner reports that FRONTLINE certainly doesn't work anymore for their two collies. Start date of event added for submission purposes only. |
| 30-May-2018 | UAE; 18UK001086; -; United Kingdom | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 17.00 Year(s)<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 01-May-2017* | N/A | D-D | As reported by the animal owner, a 17 year old male cat of unknown reproductive status, breed, weight and condition, was administered FRONTLINE PLUS SPOT ON CAT (batch P41001AW, expiry SEP 2019) via an unknown route, to an unknown site by the animal owner at an unknown dose from an unknown date for an unknown indication. The animal owner reports that they have used FRONTLINE for their cat for the last 16 years and have used FRONTLINE PLUS since it came out. They have always had total satisfaction with the product until last year when the cat still had fleas and they were forced to go to the vet to try a different brand to clear them. This year they went back to FRONTLINE PLUS, but the cat still has fleas and they have put it on properly during a dry spell so no water has been on him. The animal owner reports that they hate to see their old cat scratching so much and so uncomfortable because he still has fleas. The animal owner reports that the product is not doing the job it was meant for and that their son in law is also using the product and has the same problem. Start date added for submission purposes only. |
| 30-May-2018 | UAE; 18UK001087; -; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** 17.00 Year(s) | 1 | 1 | 1 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON; | N/A | 01-May-2018* | N/A | D-A | As reported by the animal owner, an approximately 17 year old canine of unknown reproductive status, breed, weight and condition, was administered FRONTLINE ( assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) via an unknown route, to an unknown site by the animal owner at an unknown dose from an unknown date for an unknown indication. The animal owner reports that they have used FRONTLINE for their dog for the last 16 years and have used FRONTLINE PLUS (assumed |

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| | | **Weight:** Unknown | | | | **Route:** unknown **Was the product used ok?:** Unknown to Company | | | | | FRONTLINE PLUS SPOT ON DOG M) (Batch and expiry unknown) since it came out. The animal owner reports that the dog has now passed (coded as death). Start date added for submission purposes only. |
| 30-May-2018 | UAE; 18UK001092; -; United Kingdom | **Species:** Canine **Breed:** Spaniel **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 23-May-2018 | N/A | D-D | As reported by the animal owner via Social Media, a spaniel canine of unknown age, sex, reproductive status, breed, weight and condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOGS M, batch and expiry unknown) via an unknown route to an unknown site by an unknown administrator at an unknown dose 7 days ago, estimated 23 MAY 2018, for an unknown indication. The animal owner reports that they gave the treatment to the spaniel, but it has made no difference whatsoever. They specifically spent the extra to get the plus version so as to kill the fleas but it obviously doesn't work. |
| 31-May-2018 | UAE; 18UK001096; Hampshire; United Kingdom | **Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 15.6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Yes | N/A | 01-May-2018* | N/A | D-D | As reported by the attending veterinary surgeon, Pippa, a female neutered Cocker Spaniel canine, born 17 FEB 2014, weighing 15.6 kg and in good condition, was administered FRONTLINE SPOT ON DOG (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) via an unknown route by the animal owner at an unknown dose on an unknown date as a preventative treatment. The animal owner reports that they have always used the product before. The animal owner reported to the attending vet that the are seeing 2 to 3 ticks a week. They live near a field of sheep and they are often going through the long grass. The ticks are mainly around the animal's ears. Start date of event added for submission purposes only. |
| 01-Jun-2018 | UAE; 18UK001100; Somerset; United Kingdom | **Species:** Canine **Breed:** French Bulldog **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 17.8 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Yes | 27-May-2018 | 29-May-2018 | 2 Day(s) | D-D | As reported by the veterinary nurse at the practice, Earl, a 3 year old male neutered French Bulldog canine, weighing 17.8 kg and in good condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch P62213BL, expiry AUG 2019) via an unknown route to an unknown site by the animal owner at a dose of 1 pipette on 27 MAY 2018 for an unknown indication. On 29 MAY 2018 the animal owner started cleaning the application site with salt water due to redness of the skin. The animal was seen in practice with a small area of moist dermatitis. There was no need for treatment and there has been no update since. |
| 03-Jun-2018 | UAE; 18UK001106; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 27-May-2018 | 01-Jun-2018* | N/A | D-E | As reported by the animals owner, two cats, of unknown breed, age, weight and reproductive status, were given FRONTLINE PLUS SPOT ON CATS, batch number and expiry date unknown, route, frequency and date of administration unknown, administered by the animals owner as parasite treatment. The owner reports he used to use Advocate & decided that when they saw fleas to use Frontline plus. Use started on 27 MAY 2018 and in his opinion it's not working as it doesn't do as we advertise. The owner reported that neither of the cats had responded to the treatment and that they would not be using the remaining pipette as it appeared to be useless, they felt that the product was a complete waste of money and not fit for purpose. No further information was provided. Start date of adverse event 01 JUN 2018 added for submission |

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| | | | | | | | | | | | purposes only. |
| 04-Jun-2018 | UAE; 18UK001107; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 04-Jun-2018 | 1 Week(s) | D-E | As reported by the animal owner, a female cat, of unknown breed, age, weight and reproductive status, was given FRONTLINE (assumed to be FRONTLINE SPOT ON CATS), batch number and expiry date unknown, applied topically, by the owner on 28 MAY 2018, and the owner reported on 04 JUN 2018 that they had now found fleas on the animal. No further information was provided. |
| 04-Jun-2018 | UAE; 18UK001109; Surrey; United Kingdom | **Species:** Rabbit **Breed:** Rabbit Other **Sex:** F **Sex qualifier:** - **Age:** 5.00 Month(s) **Weight:** 1.7 kg | 1 | 1 | 1 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** Unspecified vaccination; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended) | 17-May-2018 | 17-May-2018 | N/A | D-A | Rabbit was administered spot on treatment on 17 of May 2018. Next day symptoms noticed - lethargic and not eating. Rabbit was taken to Emergency Vet and was treated for potential toxic reaction, and taken home with medication and critical care to encourage eating. 4 days later, Rabbit had first seizure. Taken back to Emergency Vet and kept in hospital for 4 days/nights on IV drip and given Diazepam when required. Rabbit experienced seizures multiple times for those days. On day 7, Rabbit was taken home as eating and acting normal before and after seizures occurred. During the night, Rabbit had 7 seizures; after second one which lasted 3 minutes. Rabbit did not appear to return to normal state and seizures back more frequent.<br>Rabbit was Put to Sleep the following morning, due to suffering and status epilepticus advised by Vet.<br>UPDATE 01 JUN 2018: Further information was received by the MAH. As reported by the animals owner, Bunny a 5 month old, intact female Lionhead rabbit, of unknown weight and good health, was given FRONTLINE SPOT ON CAT (batch number and expiry date unknown) on 17 MAY 2018, administered by the animals owner, for the treatment of fleas. The owner reported that the rabbit lived with 4 cats which had caught fleas and so the rabbit caught them too. The vet advised they treat the rabbit with Advantage but the local pet shop did not have any in stock, so they were sold FRONTLINE instead. The rabbit had an unspecified vaccination at the vets the same day. The rabbit became quiet and off their food that day on 17 MAY 2018 but the vet advised that this was normal after a vaccination. The next day on 18 MAY 2018 the rabbit was lethargic, had been off its food for 24 hrs and was very quiet, not active and not running around. The owner then read the FRONTLINE box warning which said it was not suitable for rabbits. The owner took the rabbit straight to the emergency vets. A specialist was called who advised the vet to put the rabbit on IVFT and clip and |
| 02-Jun-2018 | UAE; 18UK001111; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown | 01-Jun-2018 | 01-Jun-2018* | 0 Day(s) | D-C | As reported by the animal owner, their cats (assumed 2 cats), of unknown breed, sex, age, weight and reproductive status, were given FRONTLINE (assumed to be FRONTLINE SPOT ON CAT), batch number and expiry date unknown, route unknown, given for the first time on 01 JUN 2018, administered by the animals owner, and the owner reported that one of the cats threw up (date not specified, assumed to be 01 JUN 2018). No further information was provided. |

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| | | | | | | to Company | | | | | |
| 04-Jun-2018 | UAE; 18UK001116; Beford; United Kingdom | **Species:** Canine **Breed:** Collie **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 24 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | N/A | 02-Jun-2018 | approximately 2 hours | D-E | As reported by the animal's owner, Toby an 11 year old, neutered male Rough Collie dog, weighing approximately 24 kg and of good health, was given FRONTLINE (assumed to be FRONTLINE SPOT ON DOG L) batch number: R21901BR and expiry date: 30 NOV 2020, used as spot on in 2 separate areas in-between shoulder blades & base of tail, on 02 JUN 2018, administered by the animal's owner, to treat a possible flea problem, as they had found flea dirt. Within a couple of hours of administration, the dog started to scratch, not causing self -trauma but scratching at his flanks, the owner thought that apart from flea dirt being present prior to the FRONTLINE SPOT on application, the dog wasn't scratching, so believes this was the cause, the owner also noticed that the skin was looking dandruffy. The owner reported that the dog wasn't the most mobile of dogs, (as in reaching to chew/scratch) which they thought may be the signs of arthritis, but they had not taken the dog to the vets for this. The dog was a rescued dog with no known previous history of previous flea treatment. The owner reported that they had used FRONTLINE for 30 years, as dealt with rescue greyhounds and had used FRONTLINE on them within a kennelled environment with no issues. |
| 16-May-2018 | UAE; 18UK001138; Shropshire; United Kingdom | **Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Week(s) **Weight:** - | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 01-Feb-2016* | 6 Day(s) | D-D | As reported by the animal owner, Molly, a female neutered Labradoodle (Labrador cross poodle) canine, born 04 NOV 2015, of unknown weight, was administered FRONTLINE SPOT ON DOG (assumed large dog, batch and expiry unknown) topically by the animal owner at an unknown dose, on unknown dates as preventative care. The owner reports using the product when the dog was a puppy and increasing the dose as she got heavier and that the animal has just got drowsy on the days that they've given it to her, hence they usually do it at an evening time. The animal is reportedly never drowsy enough to make her lethargic. Drowsiness was not ongoing at the time of reporting. Estimated event start date added for submission purposes only. |
| 04-Jun-2018 | UAE; 18UK001139; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 04-Jun-2018 | 1 Week(s) | D-E | As reported by the animal's owner, a cat, of unknown breed, age, weight and reproductive status, was given FRONTLINE SPOT ON CAT, batch number and expiry date unknown, applied topically on 28 MAY 2018, administered by the animal's owner, and seven days later on the 04 JUN 2018 the owner reported that the cat still had fleas. No further information was supplied. |
| 08-Jun-2018 | UAE; 18UK001142; Surrey; United Kingdom | **Species:** Feline **Breed:** European **Sex:** M **Sex qualifier:** Neutered **Age:** 10.08 Year(s) **Weight:** 6 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / | 25-May-2018 | 27-May-2018 | 2 Day(s) | D-D | UK-VMD-3409/18: On 25 May 2018 a 6kg, 10 year old male neutered DSH cat had Frontline Plus Spot-on Cat applied. On 27 May 2018 there was hair loss and mild inflammation of the skin on the back of the neck. No further information. |

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| | | | | | | Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | |
| 05-Jun-2018 | UAE; 18UK001151; West Yorkshire; United Kingdom | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 9.00 Month(s)<br>**Weight:** 3.55 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 05-Jun-2018 | 0 Day(s) | D-D | As reported by the veterinary nurse at the practice, Mushu, a 9 month old male neutered Domestic Shorthaired feline, weighing 3.55 kg and in good condition, was administered FRONTLINE SPOT ON CAT (batch and expiry unknown) topically by the animal owner at a dose of 1 vial per 1 animal on 05 JUN 2018 as a preventative treatment. The veterinary nurse reports that the animal ingested the product and started frothing (coded as foaming at the mouth) and salivating. They have washed the animals mouth out as best they can and the signs are reported to have stopped 05 JUN 2018. |
| 05-Jun-2018 | UAE; 18UK001154; -; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 12.00 Week(s)<br>**Weight:** 9.1 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 05-Jun-2018 | 2 Day(s) | D-E | As reported by the animal owner, a 12 week old male puppy canine of unknown breed and reproductive status, weighing 9.1 kg and in unknown condition, was administered FRONTLINE SPOT ON DOG S (Batch P21820A, expiry OCT 2019) via an unknown route to an unknown site by the animal owner at an unknown dose on 03 JUN 2018 for an unknown indication. The animal owner reports that they treated the animal on Sunday, today is Tuesday and the animal still has fleas. They report that they have treated the house, washed all bedding and hoovered the house twice. The animal owner has no other pets and the animal has only been out once but that it is not to say that there are no fleas in the garden from hedgehogs, cats or squirrels etc. |
| 05-Jun-2018 | UAE; 18UK001156; -; United Kingdom | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018* | N/A | D-E | As reported by the animal owner, approximately two cats of unknown age, breed, sex, reproductive status, weight and condition, were administered FRONTLINE SPOT ON CAT (batch and expiry unknown) via an unknown route, to an unknown site, by an unknown administrator at an unknown dose on an unknown date for an unknown indication. The animal owner reports that one animal is very poorly as the flea treatment has not worked. They report that the attending vet has told them that the animal is infested with fleas. Start date added for submission purposes only. |
| 06-Jun-2018 | UAE; 18UK001178; -; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 16-Mar-2018* | 01-Jun-2018* | N/A | D-E | As reported by the animal owner, a male canine of unknown age, reproductive status, breed, weight and condition, was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) via an unknown route, to an unknown site by the animal owner at an unknown dose three weeks ago (estimated as 15 MAY 2018) for an unknown indication. The animal owner reports that the animal has been treated for the last three months (estimated to start 15 MAR 2018) and still has fleas. They flea treated him three weeks ago and moved to a brand new house last week and they are still finding live fleas. Start date of event added for submission purposes only. |
| 06-Jun-2018 | UAE; 18UK001179; -; United Kingdom | **Species:** Canine<br>**Breed:** Spaniel (Cocker)<br>**Sex:** F | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | 04-May-2018* | 04-Jun-2018* | 0 Day(s) | D-E | As reported by the animal owner, a 14 month old female cocker spaniel canine, of unknown reproductive status weight and condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOGS M, batch and expiry |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Unknown<br>**Age:** 14.00 Month(s)<br>**Weight:** Unknown | | | | 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | unknown) via an unknown route by the animal owner two days ago (estimated to be 04 JUN 2018). The animal owner reports that the animal picked up fleas a couple of months ago. They bought FRONTLINE PLUS and subscribed to a monthly plan. The dog received the second monthly pipette two days ago and put it on straight away. The animal owner reports that there seems to be no noticeable difference and that the animal still has fleas . |
| 07-Jun-2018 | UAE; 18UK001183; Hampshire; United Kingdom | **Species:** Canine<br>**Breed:** Spaniel (Welsh Springer)<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 5.00 Year(s)<br>**Weight:** 24 kg | 4 | 4 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 28-May-2018 | 28-May-2018 | 0 Day(s) | D-E | As reported by the animal owner, Copper a female entire Welsh Springer Spaniel Canine, born 07 APR 2013, weighing 24 kg and in good condition, and four other canines, Willow, a 13.5 year old female entire Welsh Springer Spaniel canine weighing 25 kg, Honey a 9 year old female entire Welsh Spring Spaniel weighing 27 kg and Ruby a 10 month old female intact Welsh Springer Spaniel canine weighing 20 kg, were administered FRONTLINE PLUS SPOT ON (assumed FRONTLINE PLUS SPOT ON DOG L, batch R60719, expiry FEB 2020) topically by the animal owner at a dose of 1 pipette per 1 animal on 28 MAY 2018 as preventative care. The animal owner reports that they moved from FRONTLINE SPOT ON, which they had always used, to FRONTLINE PLUS recently and noted for the first time that there were a lot more ticks attaching. FRONTLINE PLUS was applied for the first time 28 MAY 2018. The animal owner reports that, historically apart from the odd tick attaching to the dogs, which they removed when seen, they had never seen it this bad before. This time all the dogs had clusters of 9 plus ticks on each of them and these were all over their head and face area. |
| 07-Jun-2018 | UAE; 18UK001185; -; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 3 | 3 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** Pain relief (unspecified);<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 04-Jun-2018 | 04-Jun-2018* | N/A | D-E | As reported by the animal owner, three canines of unknown age, sex, reproductive status, breed, weight and condition, were administered FRONTLINE SPOT ON DOG (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) via an unknown route, to an unknown site, by the animal owner at an unknown dose on an unknown date, two weeks late, as a preventative treatment. The animal owner reports that they have three dogs that they treat every 2 months, recently they've all got fleas. The older dog spent a night in the vets and the problem seemed to start when the animal came back. The animal owner reports that the animal doesn't seem to be scratching at all but has most of the fleas. The animal is also on pain relief daily for his joints. The owner applied the spot on on Monday 04 JUN 2018 on the two younger animals and then on Tuesday 05 JUN 2018 the animal owner went to do the older dog and realised that he was covered in them. |
| 10-May-2018 | UAE; 18UK001189; -; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 01-May-2018* | N/A | D-D | As reported by the animal owner via Social Media, approximately 2 canines of unknown age, sex, reproductive status, breed, weight and condition, were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) via an unknown route to an unknown site, by the animal owner at an unknown dose on an unknown date for an unknown indication. The animal owner reports that when they purchased FRONTLINE a few years back, to keep all of their dogs and cats (reported in linked case) free from fleas, it failed miserably. The animal owner reports that they did use the product as per the instructions. Start date of event added for submission purposes only. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 10-May-2018 | UAE; 18UK001191; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-May-2018* | N/A | D-D | As reported by the animal owner via social media, approximately two felines of unknown age, sex, reproductive status, breed, weight and condition were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown) via an unknown route to an unknown site by the animal owner at an unknown dose on an unknown date for an unknown indication. The animal owner reports purchasing FRONTLINE a few years back to keep all dogs (see linked case) and cats free from fleas and it failed miserably. The animal owner states they used the product as per the product instructions. Start date of event estimated for submission purposes only. |
| 08-Jun-2018 | UAE; 18UK001193; -; United Kingdom | **Species:** Canine **Breed:** Bulldog **Sex:** M **Sex qualifier:** Neutered **Age:** 8.50 Year(s) **Weight:** 28 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** Advocate; **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018* | N/A | D-D | As reported by a person of unknown role, Frankie an 8.5 year old, neutered male bulldog canine, weighing 28 kg and in unknown condition, was given FRONTLINE SPOT ON FOR DOGS (batch number and expiry date unknown), dose unknown, administered by an unknown person, on an unknown date, for an unknown reason. An unknown time following product administration the dog experienced an application site reaction. It is reported that the dog had received Advocate as well (assumed on the same date), Skin scrapes were negative (not specified what for) and the dog vomited after several wormers within 15 minutes (products and dates of administration not specified). Start date added for submission purposes only. |
| 08-Jun-2018 | UAE; 18UK001197; Hampshire; United Kingdom | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 4 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018* | N/A | D-D | As reported by the veterinary nurse, Marrin, a 6 year old male neutered Domestic Shorthaired feline weighing 4 kg and in unknown condition, was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown) via an unknown route, to an unknown site, by an unknown administrator, at an unknown dose, on an unknown date for and unknown indication. The veterinary nurse reports that the animal tucks paws under, rocks, salivates and is unhappy after application. This is transient and lasts for approximately one hour. The veterinary nurse reports that this happened previously with Advocate and is milder with FRONTLINE. Start date of event added for submission purposes only. |
| 09-Jun-2018 | UAE; 18UK001198; -; United Kingdom | **Species:** Canine **Breed:** Poodle (Standard) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 32 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 09-Jun-2018 | 6 Day(s) | D-E | As reported by the animal owner, a male neutered Standard Poodle canine of unknown age, weighing 32 kg and in unknown condition, was administered FRONTLINE PLUS SPOT ON DOGS L (batch and expiry unknown) topically by the animal owner at a dose of 1 dosage form on 03 JUN 2018 as a parasiticide. The animal owner reports that the animal picked up ticks whilst on holiday in Exmoor, they shampooed the animal and applied a dose of FRONTLINE PLUS. They thought that they pulled them all off, but today (09 JUN 2018) the animal owner has removed 4 from his body and 4 more from the floor. They are very large (size of raisins) ticks. The owner reports that being a very flexible standard poodle with a long body she can only apply to product to the neck as the dog can reach the base of his tail and that all the large ticks she found were on the dogs back leg armpits. The owner also reports that they have also washed everything in the house and campervan on a hot wash, sprayed the carpets and hoovered. |
| 10-Jun-2018 | UAE; 18UK001200; -; United Kingdom | **Species:** Canine **Breed:** Collie **Sex:** X **Sex qualifier:** | 3 | 3 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | 05-Jun-2018 | 05-Jun-2018 | 0 Day(s) | D-E | As reported by the animal owner, approximately three canines, Paddy, a 13 year old female collie weighing approximately 22 kg, Bert an 8.5 year old male collie weighing 25 kg approximately and Ernie, a 3 year old male Collie weighing 22 kg, were administered |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 22 - 25 kg | | | | 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | FRONTLINE PLUS SPOT ON DOGS L (batch P6210AR and expiry unknown) topically by the animal owner at a dose of 1 dosage form on 05 JUN 2018 for an unknown indication. The animal owner reports that the treatment was applied, however they have seen no improvement to their dogs wellbeing. The animal owner has been checking the animals on a daily basis and is still seeing five or six fleas on the animals. The animal owner reports that the property has also been cleaned and de flead, however they have found the treatment ineffective as their animals are still experiencing discomfort. The animal owner reports that the animals paddle in the river when it is hot but they do not swim and have access to the garden and a park. |
| 10-Jun-2018 | UAE;<br>18UK001201;<br>-; United Kingdom | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 04-Jun-2018* | 0 Day(s) | D-E | As reported by the animal owner, two felines of unknown age, sex, reproductive status, breed, weight and condition, were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown) via an unknown route to an unknown site, by the animal owner, just less than a week ago (estimated as 04 JUN 2018) for an unknown indication. The animal owner reports that the fleas are still showing up on both animals. They report that they have treated the house with a spray to kill eggs. |
| 12-Jun-2018 | UAE;<br>18UK001208;<br>-; United Kingdom | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 22-May-2018 | 0 Day(s) | D-E | As reported by the animal owner, Winston a less than 1 year old, female, Domestic shorthair feline of unknown reproductive status and of unknown weight and in unknown condition, was given FRONTLINE PLUS CAT (batch number R4051AW and expiry date APR 2020) on 22 MAY 2018, administered by the animal owner via an unknown route and using an unknown dose for flea prevention. The owner reports that they take off the collar when applying the product. The cat is an indoor cat they have not had very long. The owner reports they applied as explained on the packet. The owner reports seeing 10-20 fleas at a time, more on the cat than the dog (see linked case 18UK001214). Before using FRONTLINE PLUS in MAY the owner reports using Bob Martin as and when needed. The owners states they can't spray the home as they own tropical fish that can't be removed and can't cover the tank as they won't get oxygen. |
| 11-Jun-2018 | UAE;<br>18UK001211;<br>-; United Kingdom | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 09-Jun-2018* | N/A | D-E | As reported by the animal owner, a male cat of unknown age, reproductive status, breed and weight and in unknown condition, was given FRONTLINE PLUS SPOT ON FOR CATS (batch number and expiry date unknown) on 09 JUN 2018 for unknown duration, at unknown dose and route, administered by the animal owner for parasite control (fleas). The owner reports they have always used Frontline on their cat and he has never had fleas. A couple of weeks before 11 JUN 2018 the cat went into a cattery for a few days and when the owner collected him the owner of the cattery pointed out flea eggs on the surfaces of his pen. The owner states they were suprised that the cat had an infestation as he should have been covered by his last dose of FRONTLINE. The owner states they started using a flea comb and thoroughly cleaned and sprayed all the areas of the house where he goes. The owner goes on to state that on Saturday 09 JUN 2018 they applied a dose of FRONTLINE PLUS, unfortunately they are still finding live fleas and flea eggs on him. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 12-Jun-2018 | UAE; 18UK001214; -; United Kingdom | **Species:** Canine **Breed:** Staffordshire Terrier **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 14.000 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 22-May-2018* | N/A | D-E | As reported by the animal owner, Drifter a 9 year old, female, Staffordshire Terrier canine of unknown reproductive status and in unknown condition, weighing approximately 14 to 15 kg was given FRONTLINE PLUS SPOT ON DOG (batch number P62001AL and expiry date AUG 2019) on 22 MAY 2018, administered by the animal owner via an unknown route and using an unknown dose for flea prevention. The owner reports that they take off the collar when applying the product, the dog is inside unless walking, they applied the product as explained on the packet and that the dog does no swimming and gets bathed when needed. The owner reports seeing 10-20 fleas at a time, more on the cat (see linked case 18UK001208) and found a tick on the dog yesterday ( 11 JUN 2018). Before using FRONTLINE PLUS in MAY the owner reports using Bob Martin as and when needed. The owners states they can't spray home as they own tropical fish that can't be removed and can't cover the tank as they won't get oxygen. |
| 15-Jun-2018 | UAE; 18UK001218; -; United Kingdom | **Species:** Canine **Breed:** Pomeranian **Sex:** F **Sex qualifier:** Unknown **Age:** Unknown **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 10-Jun-2018* | 5 days | D-E | As reported by the animal owner, a Pomeranian female canine of unknown age, reproductive status, weight and condition, was given FRONTLINE PLUS SPOT ON DOG M (batch number and expiry date unknown) on 10 JUN 2018, administered by the animal owner via an unknown route using an unknown dose, as a parasiticide. The animal owner reports that they treated their Pomeranian dog (after giving her a bath) with Frontline plus on Sunday however fresh flea dirt is still appearing on her since then, and she is still scratching. The owner also reports that they think the dog has had fleas for a while so there are a lot in the home, but the owner thought this would have killed the ones on the dog by now. |
| 12-Jun-2018 | UAE; 18UK001219; Essex; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 2 - 4 kg | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 02-Mar-2018* | 12-Jun-2016 | N/A | D-E | As reported by the animal owner, 2 male cats, Bobby, a 1 year old cat, weighing 2 kg and Tommy, a 10 year old, weighing 4 kg, both of unknown breed, age, and reproductive status, were given FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown), applied to the back of the neck directly onto the skin in between the shoulder blades, used once a month. The last 4 dates of application being 02 MAR 2018, 03 APR 2018, 05 MAY 2018 and 06 JUN 2018 administered by the animal owner. The owner reported that there were still visible fleas, after last using the product which was nearly a week ago, the owner reported that the product had not worked and they were not happy with the product. The vet had told the owner that they had not applied it properly but the owner thought they had and have been using the product for many years, this was the first time they had had an issue. The owner reported that the cats spend their time indoors and in the garden, but that no wild animals come into the garden. The animals were never washed and the owner used Johnsons Home Spray too. No further information was supplied. |
| 12-Jun-2018 | UAE; 18UK001220; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** Unknown **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used** | N/A | 12-Jun-2018* | 3 Day(s) | D-E | As reported by the animal owner, approximately 2 felines of unknown age, sex, reproductive status, breed, weight and condition, were given FRONTLINE SPOT ON CAT (batch number and expiry date unknown) on 09 JUN 2018, administered by the animal owner via an unknown route at an unknown dose, for parasite control. The animal owner reports they treated their cats with FRONTLINE SPOT ON on Saturday and have treated the whole house, but found 5 fleas on one cat and 3 fleas on the other cat this morning. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Unknown to Company | | | | | |
| 15-Jun-2018 | UAE; 18UK001222; -; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** Unknown **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018* | 0 Day(s) | D-D | As reported by the animal owner, two canines of unknown age, breed, sex, reproductive status, condition, weight, were given FRONTLINE PLUS SPOT ON DOGS M (batch number and expiry date unknown) on 01 JUN 2018 (date is approximate) at an unknown dose, administered by the owner, for parasite control . The owner reports that they have always bought FRONTLINE for their 2 small dogs. This time they bought FRONTLINE PLUS as they thought it would be more effective . The owner states they put the product on nearly 2 weeks ago only to find they still have fleas. The owner states they have had to put the product on again to see if it will rid them of the fleas. The owner states they never buy the product online, always at their chemist. Start date for submission purposes only |
| 14-Jun-2018 | UAE; 18UK001239; -; United Kingdom | **Species:** Canine **Breed:** Collie **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 13.9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** No (Overdose) | N/A | 14-Jun-2018 | 1 Day(s) | D-C | As reported by the attending veterinary surgeon, Alba, an approximately 2 year old, neutered female Collie crossbreed dog of unknown reproductive status, weighing 13.9 kg and in unknown condition, was given FRONTLINE COMBO SPOT ON DOG L (batch number and expiry date unknown) on 13 JUN 2018, administered by the animal owner as a parasiticide. The attending veterinary surgeon reports that the dog was given a 20-40 kg dose (accidental overdose). On 14 JUN 2018, in the afternoon the dog experienced tremors, shaking and vomiting. The veterinary nurse at the practice reported that the dog had also eaten old cream from the fridge on the afternoon of 14 JUN 2018 and that the dog's eyes were flickering .The dog was not on any other meds and had not eaten anything else. The dog was sick 4 times on the way to the exam on 14 JUN 2018. No nystagmus on exam. The veterinary nurse states the differential diagnosis was mycotoxicosis from the cream mould/ FRONTLINE COMBO toxicity. Dispensed DIAZEPAM to be taken home, owners couldn't do bloods so took dog home. |
| 18-Jun-2018 | UAE; 18UK001251; Wiltshire; United Kingdom | **Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** - **Age:** 5.75 Year(s) **Weight:** 37.7 kg | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** AFOXOLANER 150 MG / MILBEMYCIN OXIME 30 MG CHEWABLE TABLETS; **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 18-Jun-2018 | approximately 6 Week(s) 6 Day(s) | D-C | As reported by the attending veterinary surgeon, Hazel, a 5 year 9 month female intact German Shepherd dog weighing 37.7 kg and in good condition, was administered NEXGARD SPECTRA XL (batch and expiry unknown) orally by the animal owner at a dose of 1 dosage form on 18 JUN 2018 as an antiparasiticide. The attending vet reports that the animal was also given FRONTLINE (assumed FRONTLINE SPOT ON DOG XL, batch and expiry unknown) in MAY 2018 (assumed 01 MAY 2018). The animal was given NEXGARD SPECTRA at 11 am. At 3 pm the pet owner called the practice to report that the animal was off its back legs, panting, collapsed, having seizure type activity. The animal presented to the practice and was pawing at the face. The attending vet suspected that the animal had had a partial seizure and gave oxygen. At 3:30 pm the signs had resolved but the animal was still panting.<br>UPDATE 24 JUL 2018: The attending vet reports that the patient was twitching and unsettled for 3 days after administration of NEXGARD SPECTRA. The animal owner reported to the attending vet that the animal is still 'funny' on one leg (coded as gait abnormality). The animal was last seen on 22 JUN 2018. |
| 15-Jun-2018 | UAE; 18UK001252; | **Species:** Canine **Breed:** Borzoi | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT | N/A | 11-Jun-2018 | 5 days | D-C | As reported by the attending veterinary surgeon, Zoya, a 10 month old, intact, female, non-pregnant non-lactating Borzoi canine |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | Leicestershire; United Kingdom | (Russian Wolfhound)<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 10.00 Month(s)<br>**Weight:** 32.5 kg | | | | ON DOG<br>**Other products used:** Unspecified NSAID; Codeine;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | weighing 32.5 kg and in good condition, was given FRONTLINE SPOT ON DOG M (batch number and expiry date unknown) on 06 JUN 2018 by the animal owner, applied topically between the shoulder blades as a flea treatment. On 10 JUNE 2018 the dog was groomed and was fine. On 11 JUN 2018 the dog was unsettled. On 13 JUN 2018 the attending veterinary surgeon reports that the dog was painful, with a suspected trapped nerve. It was difficult to extend the legs forward. The thoracic spinal area was tense. The dog came into the practice on 13 JUN 2018, reacted to pain in shoulder blades like it was being bitten or stabbed, so they thought it was muscle pain as there were no changes on the skin. NSAIDS and codeine were given, but the codeine made her hyper and vocalise a lot, she was very unsettled with it. On 14 JUNE 2018 the attending veterinary surgeon reports that the dog came in for another examination but the vet had to sedate it as she couldn't touch it/examine it as the dog was too painful. The attending veterinary surgeon states that the dog is extremely sensitive so may have been over-reacting dramatically. The skin appeared ulcerated with excoriation. The dog was given Dexadreson IV, the area was cleaned with Hibiscrub and Flamazine was applied. The dog was very agitated had a high pitch voice, was trying to snap and was very reactive. The vet could feel scab, which was described as moth eaten and deep through to subcutis. There were itchy spots around the body. The previous week the dog had ticks and was described as over the top, melodramatic, chewing at the sides and had linear lesions along back. On 15 JUN 2018 the attending veterinary surgeon reports that the dog was much more comfortable but still tender. The area had more excoriation. The attending vet didn't remove the scabs, overall looking bit better and happy in herself. On |
| 17-Jun-2018 | UAE; 18UK001255; -; United Kingdom | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018* | N/A | D-D | As reported by the animal owner, a female feline of unknown age, reproductive status, weight and condition was given FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown) on an unknown date by the animal owner for an unknown reason. The route and dose of administration are unknown. The animal owner reports that they used FRONTLINE PLUS, when they put it on their cat it burnt her fur off leaving a very sore and bald patch . The animal owner reports taking the cat to the vet as she has also been very quiet. Start date for submission purposes only. |
| 18-Jun-2018 | UAE; 18UK001259; -; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 18-Jun-2018 | approximately 3 Day(s) | D-D | As reported by the animal owner, a canine of unknown age, sex, reproductive status, breed, weight and condition, was administered FRONTLINE PLUS SPOT ON DOG (assumed FRONTLINE PLUS SPOT ON DOGS M, batch and expiry unknown) via an unknown route to an unknown site by the animal owner at an unknown dose 2-3 days ago (estimated 15 JUN 2018) for an unknown indication. The animal owner reports that the fleas are still there. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 19-Jun-2018 | UAE; 18UK001261; Greater Manchester; United Kingdom | **Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** F **Sex qualifier:** Unknown **Age:** 3.00 Month(s) **Weight:** 0.9 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Overdose) | 17-Jun-2018 | 17-Jun-2018 | approximately 2 hours. | D-C | As reported by the attending veterinary surgeon, Julia, a 3 month old female intact Jack Russell Terrier cross canine unknown, weighing 0.9 kg and in unknown condition, was administered FRONTLINE PLUS SPOT ON DOGS S (Batch and expiry unknown) topically by the animal owner at a dose of 1 dosage form on 17 JUN 2018 for an unknown indication. The attending vet reports that within a couple of hours the animal was breathing heavily. The attending vet saw the animal on 18 JUN 2018, and the animal was still panting a bit. The animal owners declined further investigation. On 19 JUN 2018 the animal owner reported vomiting and the animal was showing 7 to 10 percent dehydration, abdominal distension, was passing watery diarrhoea with fresh blood and was generally unwell. According the owner the animal is 3 months old, however the attending vet feels that the animal is 6 to 8 weeks old. |
| 19-Jun-2018 | UAE; 18UK001267; -; United Kingdom | **Species:** Canine **Breed:** Spaniel **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 19-Jun-2018 | 0 Day(s) | D-E | As reported by the animal owner, Murphy, a Spaniel canine of unknown age, breed, sex, reproductive status, weight and condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOGS M, Batch and expiry unknown) topically by the animal owner at a dose of 1 dosage form on 19 JUN 2018 as they had seen fleas on the animal. The animal owner reported that they bought the product on Sunday and put it on the animal. It is unknown if the product was used correctly. Over 48 hours later the animal owner can still see fleas. The animal hasn't been treated for a long while before this as they haven't seen any fleas. |
| 20-Jun-2018 | UAE; 18UK001270; Surrey; United Kingdom | **Species:** Canine **Breed:** Border Collie **Sex:** F **Sex qualifier:** Neutered **Age:** 3.25 Year(s) **Weight:** 24 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 17-Nov-2016 | 3 Day(s) | D-C | UK-VMD-3730/18: On 14 Nov 2016 a 3.2 year old, 24kg border collie female neutered was treated with Frontline Combo Spot-on Dog L. On 17 Nov 2016 the dog was frothing from mouth, whining, urinated. Collapsed on side, shivering and stiffness. Returned to normal after 1 minute. Four further fits within the next 20 days. Nothing further. |
| 18-Jun-2018 | UAE; 18UK001271; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown | N/A | 01-Jun-2018* | N/A | D-D | As reported by the animal owner, approximately 2 felines of unknown sex, age, weight, reproductive status, breed and in unknown condition, were given FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown) by the animal owner via an unknown route and at an unknown dose on an unknown date for parasite control. The animal owner reports that they have been using FRONTLINE PLUS SPOT ON CAT treatment which inhibits the development of flea eggs. They state they must be doing something wrong or missing something as they have never had a problem with fleas, until they started using FRONTLINE. The animal owner states they have followed the instructions religiously and their cats now have fleas even a week after treating them. Start date for submission purposes only. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | to Company | | | | | |
| 18-Jun-2018 | UAE; 18UK001273; -; United Kingdom | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018 | N/A | D-E | As reported by the animal owner, a canine of unknown age, sex, weight, breed, reproductive status, and in unknown condition, was given FRONTLINE PLUS SPOT ON DOG M (batch number and expiry date unknown) via an unknown route at an unknown dose by the animal owner on an unknown date. The animal owner reports that they bought this product for their dog and it doesn't work at all. Start date for submission purposes only. |
| 18-Jun-2018 | UAE; 18UK001274; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 3.5 - 4.2 kg | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 25-May-2018* | 0 Day(s) | D-E | As reported by the animal owner, Jazz and Gadu, two male felines of unknown age, breed, reproductive status, weighing 3.5 kg and 4.2 kg respectively, and in unknown condition were treated with FRONTLINE SPOT ON CATS (batch number P41001AW expiry date unknown) on approximately 25 MAY 2018 by the animal owner topically for an unknown purpose. The animal owner reports that the product did not work at all and they had to take their cats to the veterinary surgery and buy further treatment. The animal owner reports that the veterinary surgery informed them that they observe this happening a lot with FRONTLINE recently due to possibly fleas developing tolerance for the drug. The animal owner states they have kept and looked after animals all their life and are confident that it is not an application problem. The animal owner also reports that they applied FRONTLINE between the shoulder blades or on the neck, ensuring direct contact to the skin, avoiding fur getting in the way. The animal owner further reports that Jazz, the one who had this problem more is always in the house. Gadu often spends time in the garden. He is a tripod so he cannot go to other gardens. The animal owner states that another cat comes to the garden sometimes. |
| 19-Jun-2018 | UAE; 18UK001277; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 12-Jun-2018* | 0 Day(s) | D-E | As reported by the animal owner, a male feline of unknown age, weight, breed, reproductive status, and in unknown condition, was given FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown) on approximately 12 JUN 2018, administered by the animal owner. The animal owner reports that they applied FRONTLINE PLUS SPOT ON CAT to their cat one week ago and while the owner kept him outside, they used Raid Flea Foggers in their shop because that's where the cat stays when the owners are not at home and at night. The animal owner reports that they noticed the yard had fleas so they treated that and got it under control. The animal owner further states that they noticed they had a few in the house so they have been treating their home by vacuuming and spraying and made homemade flea traps with dish detergent. The animal owner states that they would come out of their shop and would have fleas on their socks and shoes and the cat was scratching like crazy again. The animal owner states that today they are using the foggers again and gave their cat a bath with dawn dish detergent. The animal owner states you would not believe the fleas on the cat after they got him wet and that they need help. The animal owner reports that after the bath and the cat is dry, they still see active fleas on him . The owner has used a flea comb and dipped it in dish detergent when they get |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | fleas on the comb. |
| 19-Jun-2018 | UAE; 18UK001279; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 10-Jun-2018* | 0 Day(s) | D-D | As reported by the animal owner, a male feline of unknown breed, age, weight, reproductive status, and in unknown condition, was given FRONTLINE SPOT ON CAT (batch number and expiry date unknown) on 10 JUN 2018 by the animal owner. The animal owner reports that they used FRONTLINE SPOT ON CAT 9 days ago and may have been overdue as had a few bites. The animal owner noticed lots of dirt in his white fur tonight and decided to give him a bath and shampoo. When the animal owner was washing him they realised he had lots of fleas on him. When the animal owner took him out it was obvious that they were biting him and he was in distress. The animal owner further reports that he is a big cat and has been staying out a lot in warm weather. |
| 20-Jun-2018 | UAE; 18UK001283; Greater London; United Kingdom | **Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 29.4 kg | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Gabapentin; Loxicom; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 14-Jun-2018 | 15-Jun-2018 | 1 Day(s) | D-A | As reported by the attending veterinary surgeon, Honey, a female neutered Golden Retriever canine, born 30 JUN 2006, weighing 29.4 kg and in good condition, was administered FRONTLINE PLUS SPOT ON DOGS L (batch R60906AR, expiry MAR 2020) topically by the animal owner at a dose of 1 pipette on 14 JUN 2018 as preventative care. The animal has a history of Arthritis and received Gabapentin and Loxicom. The following day, 15 JUN 2018, the animal was not herself and was lethargic but her appetite was good. Bloods were taken on this day and ALKP was 303 (elevated slightly) and Urea was 15.9 (elevated), PCV was 32 percent Platelets were 138 and Albumin was 30. The animal was not treated and was better over the weekend. On Monday, 18 JUN 2018 the animal had a walk and was eating, and the animal owner took the other dogs out. When they returned the animal was collapsed lying laterally. The animal had abdominal discomfort - nothing abnormal was detected on abdominal cystocentesis - no blood back - but the vet suspected a bleed. The animal's PCV was 27 percent and Platelets was 78 percent (both dropped from previous bloods), WBC were down to 12 and Albumin 32. The animal's temperature was 37.9 and was only lifting the head, was tachypnoeic with abdominal distension and pale mucus membranes. The attending vet reports that the animal was a very quiet dog in nature who had been 'old since a puppy and was not very emotionally resilient. The animal owner opted for the animal to be put to sleep (euthanased) on a quality of life basis. No post mortem examination and no scans of abdomen. |
| 19-Jun-2018 | UAE; 18UK001285; -; United Kingdom | **Species:** Canine **Breed:** Mixed Breeds / various **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 10 kg* | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018* | N/A | D-E | As reported by the animal owner, one American cocker spaniel canine and one poodle canine, both of unknown age, sex, reproductive status and in unknown condition, both weighing less than 10 kg, were given FRONTLINE PLUS SPOT ON DOGS S (Batch number P61326AL expiry date MAY 2019) on an unknown date by the animal owner. The animal owner reports that they purchased a 3 pack of FRONTLINE PLUS SPOT ON DOGS S from the chemist, and have noticed approximately 5 fleas on the white American Cocker Spaniel. Start date for submission purposes only. |
| 20-Jun-2018 | UAE; 18UK001286; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT | 01-Jan-2016* | 06-Jun-2018* | N/A | D-E | As reported by the owner of the animal, Mister Cuddles, a 3 year old male feline of unknown breed and reproductive status, weighing 6 kg and in unknown condition, was administered |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 6 kg | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | FRONTLINE SPOT ON CAT (batch and expiry unknown) topically by the animal owner on the back of the neck at a dose of 1 pipette every 4 weeks for the last 2 years (estimated 01 JAN 2016) as a flea treatment. There was a 5 week gap in treatment between March and April 2018. The animal owner reports that they have used the product for this time without problems, but 2 weeks ago (estimated as 06 JUN 2018) they applied the product and it did not work. They report that they followed the instructions as they always do but the animal still had fleas. The animal owner reports that they are disappointed with the product and cannot understand how it simply did not work. The animal owner reports that they treated the house (Indorex used monthly) at the same time as they treated the animal, and that the animal is an indoor cat but that they suspect that they brought them in from the animal that lives next door who loves rubbing against their legs. The animal owner reports that they intend to change to another product. |
| 19-Jun-2018 | UAE; 18UK001287; Shropshire; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jun-2003* | 01-Jun-2018* | N/A | D-E | As reported by the animal owner, one male canine of unknown age, weight, reproductive status, breed and in unknown condition, was given FRONTLINE SPOT ON DOG L (batch number and expiry date unknown) on an unknown date by the animal owner via an unknown route for parasite control. The animal owner reports that they purchased 2 cat (see linked case 18UK001288) and 1 dog pipettes. The animal owner states that they haven't had fleas for 15 years, the dog went to the vet and came back scratching. The dog has started chewing and he's losing his fur around the top of his tail so they are really aggravating him. The animal owner further states that they used FRONTLINE SPOT ON DOG 15 years ago and it worked quite quickly and got rid of the fleas. Start date for submission purposes only. |
| 19-Jun-2018 | UAE; 18UK001288; Shropshire; United Kingdom | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jun-2003* | 01-Jun-2018* | N/A | D-D | As reported by the animal owner, approximately 2 felines of unknown age, sex, weight, reproductive status, breed and in unknown condition, were given FRONTLINE SPOT ON CAT (batch number and expiry date unknown) on an unknown date by the animal owner via an unknown route for parasite control. The animal owner reports that they purchased 2 cat and 1 dog pipettes. The animal owner states that they haven't had fleas for 15 years, the dog went to the vet and came back scratching (reported in linked case 18UK001287), then the cats started and noticed they had fleas. Start date for submission purposes only. |
| 20-Jun-2018 | UAE; 18UK001292; -; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018* | N/A | D-D | As reported by the animal owner, a female canine of unknown age, reproductive status, breed, weight and condition, was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) via an unknown route by the animal owner at a dose of 1 dose every two months from an unknown date for flea treatment. The animal owner reports that the animal has had two ticks. The first one had fallen off, but the second one was new and they smothered it in Vaseline and then pulled it out using their fingers. The animal owner reports that they can feel a lump below the skin and are worried that it may be the head, and that they are disappointed that the ticks have been able to survive despite regularly using the treatment. Start date of event added for submission purposes only. |
| 21-Jun-2018 | UAE; 18UK001294; | **Species:** Canine<br>**Breed:** Greyhound | 1 | 1 | 0 | **Product used:** FIPRONIL | 28-May-2018 | 01-Sep-2017 | N/A | D-D | As reported by the SQP at the store, Blue, a 9 year old female neutered Greyhound cross canine unknown, weighing 22 kg and in |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | Cornwall; United Kingdom | **Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 9.00 Year(s)<br>**Weight:** 22 kg | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** FIPRONIL SPOT ON DOG;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | good condition, was administered FRONTLINE PLUS SPOT ON DOGS L (batch and expiry unknown) topically by the animal owner at a dose of 1 dosage form on 28 MAY 2018 as a preventative. It is reported that the animal had a really bad skin reaction and lost loads of the hair on its back, down towards the tail and lumbar area. It looked like a flea allergy reaction and the animal made itself bleed and lost a lot of weight through scratching and stress according to the animal owner's report. Approximately five to six days after the initial reaction starting on 29 MAY 2018, the animal went to the vets, and had been back weekly since. The attending vet reported that the animal had been seen previously for a very similar skin issue on 01 SEP 2017 - seen for itchy and irritated skin, self trauma, and the animal owners claimed to have applied FRONTLINE, but that there were lots of fleas found around the back end of the animal. The attending vet gave Bravecto and antibiotics and antiinflammatories. On 29 MAR 2018 the animal weighed 23.9 kg, and was seen for a similar complaint - self inflicted trauma over the rump. The animal's anal glands were also very full and so were expressed and Isaderm gel, Antibiotics and Dexadreson were given. The animal was seen on 04 JUN 2018 and the animal owner reported that they used FRONTLINE PLUS one week ago. The animal was itchy and depressed, and on examination a severe Flea Bite Allergy was suspected - lesions caudal hindlimbs and dorsal rump. There were no fleas seen, but the animal was treated for fleas and Apoquel and Antibiotics were dispensed. On 11 JUN 2018 the animal weighed 22.7 kg and was much improved. The skin was still a bit scurfy and so they continued with the antibiotics. On 19 JUN 2018 the animal was seen again and weighed 23.3 kg and the animal owner expressed concern that they were going to lose the |
| 20-Jun-2018 | UAE; 18UK001299; Middlesex; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 13-Jun-2018* | 0 Day(s) | D-E | As reported by the animal owner, a male canine of unknown age, breed, weight, reproductive status and unknown condition was given FRONTLINE SPOT ON DOG M (batch number and expiry date unknown) by the animal owner on an unknown date and for an unknown reason. The animal owner states that they used FRONTLINE on their dog last week (estimated as 13 JUN 2018, the correct strength) and he has fleas. His bedding is washed and sprayed with flea spray from vet. Start date for submission purposes only. |
| 21-Jun-2018 | UAE; 18UK001305; -; United Kingdom | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018* | N/A | D-D | As reported by the animal owner, a female canine of unknown age, breed, reproductive status, weight and in unknown condition, was given FRONTLINE ( assumed FRONTLINE SPOT ON DOG M, batch number and expiry date unknown) on an unknown date by the animal owner via an unknown route at an unknown dose for parasite control. The animal owner states that they treated their dog with FRONTLINE using the correct dosage for her size as a precaution- she didn't have any fleas. Two weeks after treatment she is riddled with hundreds of fleas and has now got sores due to itching. Start date for submission purposes only. |
| 21-Jun-2018 | UAE; 18UK001308; -; United Kingdom | **Species:** Canine<br>**Breed:** Cockapoo<br>**Sex:** M | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | N/A | 17-Jun-2018 | N/A | D-E | As reported by the animal owner, Cookie, a male Cockapoo canine of unknown reproductive status, age, weight and condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown) via an unknown |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | route by the animal owner at an unknown dose 4 days ago (17 JUN 2018) as the animal had picked up some fleas. The animal owner reports that the animal had picked up the fleas about a month ago when the had treated the animal with another product that contains the same active ingredient as FRONTLINE. This didn't really work and after washing the animal with medicated flea shampoo and using a dust comb with limited success, they decided to buy FRONTLINE PLUS and applied it correctly as per the instructions. The animal owner reports that after the treatment they were still having the fleas running around the animal, with just as much energy as they previously had. The animal owner has now, after waiting 48 hours as suggested in the instructions, washed the animal in herbal flea shampoo and rinsed with a white vinegar solution, which has seen the flea population decrease appreciably. The animal owner reports that they are now wiping the animal's coat with a cider vinegar solution and using the flea comb regularly throughout the day, and report that this methodology has been far more successful than using FRONTLINE PLUS. The animal owner reports that they have also been treating the areas and bedding where the animal sits and lies with flea sprays whilst treating the animal as well. |
| 22-Jun-2018 | UAE; 18UK001319; -; United Kingdom | **Species:** Canine<br>**Breed:** Spaniel (Cocker)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** No (Overdose) | N/A | 10-Jun-2018* | 0 Day(s) | D-E | As reported by the owner of the animal, a Cocker Spaniel canine of unknown age, sex, reproductive status, weight and condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOGS M, batch and expiry unknown) via an unknown route by the animal owner at the beginning of JUN 2018 (estimated 01 JUN 2018) for an unknown indication. The animal owner reports that after 10 days, they were still seeing fleas and so they applied another pipette to the back of the neck and middle of the back. The animal owner is still seeing fleas now. The animal is a working dog that lives outside in the barn. The animal owner also has cats but these do not go into the barn. The animal does not come in to contact with other dogs (but does go to classes) and doesn't go near the cats. |
| 23-Jun-2018 | UAE; 18UK001320; -; United Kingdom | **Species:** Canine<br>**Breed:** Spaniel (Cocker)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 9.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 05-Jun-2018 | 0 Day(s) | D-E | As reported by the animal owner, a 9 year old female Cocker Spaniel canine, of unknown reproductive status, weight and condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOGS M, batch and expiry unknown) via an unknown route by the animal owner 18 days ago (05 JUN 2018) as the animal had fleas. The animal owner reports that now, more fleas than ever have appeared on the animal. |
| 24-Jun-2018 | UAE; 18UK001321; Essex; United Kingdom | **Species:** Canine<br>**Breed:** Spaniel (Cocker)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** 13.600 - | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products | 04-Dec-2017 | 18-Jun-2018* | 4 Week(s) 5 Day(s) | D-E | As reported by the animal owner, Willow, a 1 year old female Working Cocker Spaniel canine, weighing 13.6 kg and Molly a 10 year old female English Springer Spaniel canine weighing 15.4 kg, both in unknown condition, were administered FRONTLINE PLUS SPOT ON DOG M (batch P62213BL and P40802AW, and expiry unknown) topically in three different places on the neck and shoulders, by the animal owner at a dose of 1 dose every 8 weeks from 04 DEC 2017 for parasite control. The animal owner reports that they have five cats and 2 dogs all being treated with |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | 15.4 kg | | | | **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | | | | | FRONTLINE PLUS, and that they have been treated regularly for a year with the product (cats assumed to receive FRONTLINE PLUS CAT). There was a treatment gap for the cats of more than 5 weeks between February and April. This past week the animal owner has noticed fleas on one of the dogs, Willow, but that they cannot find any on the other animals. They have been combing them daily to monitor, and report that they removed six plus fleas off Willow's tummy. The animal owner wants to put on another dose, but they do not want to harm the animal. The animal owner reported that the dog goes in water occasionally and she rarely has a bath, 1-2 times a month, but is brushed daily. They also have other dogs coming and going from the house, and they know that one of those dogs had fleas. The animal owner reports that the animals are in the house and garden all day every day as they work from home. They walk the animals at the park and in woodland and in the countryside and the house backs onto fields and they often have wild foxes in the garden, and one of the cats quite often brings home wild rabbits. The animal owner also reports that their neighbours all have cats. The animal owner has not been aware of being bitten by fleas and they used a home protection last SEP 2017, that was supposed to last a year. |
| 25-Jun-2018 | UAE; 18UK001327; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 4 | 3 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018* | N/A | D-E | As reported by the animal owner, three felines, of unknown age, sex, reproductive status, breed, weight and condition, were administered FRONTLINE SPOT ON CATS (Batch and expiry unknown) via an unknown route to an unknown site by the animal owner at an unknown dose on an unknown date for an unknown indication. The animal owner reports that she recently purchased FRONTLINE SPOT ON FOR CATS and applied the pipette individually to three of their cats (total number estimated as 4) and followed the guidelines for this. After 48 hours the animal owner noticed that the cats were scratching excessively around the neck and head. The animal owner checked the area with a flea comb and realised that all the animals had a lot of fleas in the area. The animal owner does not think the product has worked. Start date added for submission purposes only. |
| 25-Jun-2018 | UAE; 18UK001328; South Wales; United Kingdom | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 4 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | 01-Jan-2008* | 01-Apr-2018* | N/A | D-D | As reported by the animal owner, Benjy, a 15 year old male Domestic Shorthair feline of unknown reproductive status and condition, and weighing just under 4 kg, was administered FRONTLINE SPRAY (batch P05903A and expiry unknown) topically to the back, from the base of the neck to the tail, by the animal owner at a dose of 8 pumps (2 pumps / kg) every 6 weeks since 2008 (estimated 01 JAN 2008) for fleas. The animal owner reports that they bought the 100 ml bottle from the vets, but that they were disappointed as after APR, MAY and JUN 2018 they were still seeing fleas. The animal owner used an old nit comb and since 12 APR 2018 the animal owner has killed 28 fleas himself. The animal owner reports that they sprayed the animal on Sunday 17 JUN 2018 and then put the nit comb through him on the morning of 21 JUN 2018, and got 3 fleas from the animal's back. The animal owner reports that the animal spends most of it's time indoors and in the garden, there are no wild animals or farm animals in the area, the animal does not go swimming and is not bathed, the product is not applied when the animal is wearing a collar, no one in the home is being bitten and there have been no changes to the home environment in the last six months. The animal owner reports that they purchased FRONTLINE HOMEGARD from their vets and have used it every six weeks |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | from 2008 when they got the animal. |
| 27-Jun-2018 | UAE; 18UK001336; Surrey; United Kingdom | **Species:** Canine **Breed:** Canine Crossbred **Sex:** - **Sex qualifier:** - **Age:** - **Weight:** - | - | - | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 20-Jun-2018 | 12 Day(s) | D-D | UK-VMD-3929/18: Reporter states that 5 dogs have been treated with Frontline Combo Spot On on 8 June 2018 - product size not specified and weight of dogs not available. From 20 June 2018 there are still has live fleas on dogs and no dead fleas seen at all. Nothing further. |
| 27-Jun-2018 | UAE; 18UK001340; Kent; United Kingdom | **Species:** Canine **Breed:** Schnauzer (Miniature) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 9.000 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 21-May-2018 | 20-Jun-2018* | 2 Day(s) | D-D | As reported by the animal owner, Bazil, a 5 year old male neutered Miniature Schnauzer canine, weighing 9 kg and in good condition, was administered FRONTLINE PLUS SPOT ON DOG M (batch P62001AR, expiry AUG 2019) topically by the animal owner at a dose of 1 pipette on 21 MAY 2018 and 18 JUN 2018 as preventative care. The animal owner applied the product when they saw a flea on Bazil on 18 JUN 2018 and also treated the house with Homegard. The animal owner reports that the animal was off colour and they took the animal to the vets last week (date not known) because it was miserable, off food and very reactive like he was getting bitten. The animal owner reports that the attending vet felt that it was the animal's anal glands and so they were emptied and the animal was given steroids. The animal owner does not feel that this was the cause of this recent bout of being off colour as they think it is the fleas. The animal owner did not give permission for the MAH to contact the attending vets, and reports that the animal has improved since they removed the fleas from the animal with a flea comb. The animal owner reports that they home bathed the animal on 18 MAY 2018. The animal owner also treated their other animal which is reported in the linked case. |
| 27-Jun-2018 | UAE; 18UK001341; Kent; United Kingdom | **Species:** Canine **Breed:** Schnauzer (Giant) **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 36 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Incurin; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 21-May-2018 | 26-Jun-2018* | 8 Day(s) | D-E | As reported by the animal owner, Lilly, a 9 year old female neutered Giant Schnauzer canine, weighing 36 kg and in good condition, was administered FRONTLINE PLUS SPOT ON DOG L (batch P62109AR, expiry AUG 2019) topically by the animal owner at a dose of 1 pipette on 21 MAY 2018 and 18 JUN 2018 as preventative care. The animal has a history of urinary incontinence and receives Incurin. The animal owner applied the product when they saw a flea on the other animal in the household (see linked case) on 18 JUN 2018 and also treated the house with Homegard. The animal owner feels that despite using FRONTLINE products on the animals for years, they have never witnessed such a huge amount of fleas. Last night alone the animal owner picked off 30 fleas with a flea comb, and reported that they feel that they have wasted their money. Start date added for submission purposes only. |
| 27-Jun-2018 | UAE; 18UK001348; -; United Kingdom | **Species:** Canine **Breed:** German Shepherd Dog **Sex:** U **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | N/A | 22-Jun-2018 | 23 Day(s) | D-E | As reported by the animal owner, Rory a 3 year old German Shepherd canine of unknown sex, reproductive status and in unknown condition, weighing 36 kg, was given FRONTLINE PLUS SPOT ON DOGS M (batch number and expiry date unknown) by the animal owner via an unknown route on 30 MAY 2018 for an |

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| | | Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 36 kg | | | | **Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | unknown reason. The animal owner owns 1 dog and 9 cats (see linked case 18UK001349). The animal owner reports that they applied FRONTLINE PLUS to the dog on 30 MAY 2018. On 22 JUN 2018 the animal owner reports that they noticed that the dog was scratching and itchy. On 23 JUN 2018 the dog was taken to the vet. Vet treated the dog with BRAVECTO. Hedgehogs and rabbits visit the garden. The animal owner reports that her ankles have been bitten. There have been gaps in treatment of the cats recently because they are house cats (though with an out door run). The animal owner has used ACCLAIM and washed the bedding above 60c. |
| 27-Jun-2018 | UAE;<br>18UK001349;<br>-; United Kingdom | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 6.00 Year(s)<br>**Weight:** 4.2 kg | 9 | 9 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** Bravecto;<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 19-Jun-2018 | 20 Day(s) | D-D | As reported by the animal owner, Timothy an approximately 6 year old male Domestic Shorthair feline of unknown reproductive status and in unknown condition, weighing 4.2 kg, was given FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown) on 30 MAY 2018 by the animal owner via an unknown route for an unknown reason. The animal owner reports that they applied FRONTLINE PLUS to the cats. The owner owns 9 cats and 1 dog in total (see linked case 18UK001348). On 19 JUN 2018 the animal owner reports that Timothy appeared to have dry eczema on back legs with definite fur loss (and still hasn't got his trousers back now), two tiny bald patches on head, the owner thinks this is due to fleas or a fight. Timothy fights/has squabbles with the other cats, they bang each other on the head with a paw. The animal owner doesn't think it was as a result of the FRONTLINE PLUS SPOT ON CATS as the bald patches weren't on the application site, they were above the eyes. On 23 JUN 2018 the animal owner reports that Timothy was scratching so husband took him to the vet. Vet treated him with BRAVECTO. Cat treated on Saturday at surgery at 12pm with BRAVECTO and by 11pm that night was very ill and has since been very ill. He has been back to the vets for bloods. Liver function isn't that different to what we expect, kidneys less. Looking poorly and barely eaten since the BRAVECTO. BRAVECTO was not a product she wanted to use but husband took the cat to the vet. The animal owner has seen that scratching all the time and inappetance is on the BRAVECTO datasheet. The animal owner reports being told that FRONTLINE PLUS SPOT ON CATS cannot be given until 6 weeks has passed. FRONTLINE PLUS SPOT ON CATS isn't working as now all the other cats are getting itchy. Hedgehogs in the garden all over the garden and rabbits. The animal owner reports that her ankles have been bitten. She has left gaps in treatment of the cats recently because they are house cats (though with an out door run). |
| 28-Jun-2018 | UAE;<br>18UK001351;<br>-; United Kingdom | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 24-Jun-2018* | N/A | D-D | As reported by the animal owner, a male neutered domestic shorthair feline of unknown age, weight and in unknown condition, was given FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown) on 24 JUN 2018 by the animal owner via an unknown route at an unknown dose for parasite control. The animal owner reports that they applied FRONTLINE PLUS but it hasn't worked. The animal owner states they last applied it a few months ago. The cat does go outside and people are being bitten. |

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| 28-Jun-2018 | UAE; 18UK001356; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 01-Jun-2018* | N/A | D-E | As reported by the animal owner, a feline of unknown breed, age, weight, sex, reproductive status, and in unknown condition, was given FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown) on an unknown date via an unknown route at an unknown dose by the animal owner for parasite control. The animal owner reports that they are still finding live fleas on their cat after using FRONTLINE PLUS. Start date for submission purposes only. |
| 28-Jun-2018 | UAE; 18UK001358; -; United Kingdom | **Species:** Feline **Breed:** - **Sex:** X **Sex qualifier:** Unknown **Age:** 2.92 Year(s) **Weight:** 5.9 - 7.4 kg | 2 | 2 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jun-2017* | 26-Jun-2018* | 13 Day(s) | D-D | As reported by the retail outlet, Chandon, a two year 11 month old male Maine Coon feline of unknown reproductive status, weighing 7.4 kgs and in unknown condition, and Moet, a 3 year old female Maine Coon feline weighing 5.9 kgs and of unknown reproductive status, were given FRONTLINE SPOT ON CAT (batch number R21801AX expiry date NOV 2020) from 24 MAR 2018 every 4 weeks by the animal owner topically to the back of the neck for parasite control. The retail outlet reports that the animal owner complained to them following purchasing 2 x 6 pack of FRONTLINE SPOT ON CAT because there are ticks attached on the treated cats and they aren't dying, they are getting bigger. The retail outlet reports that the customer has taken cats to vets and they said this shouldn't be happening. The attending veterinary surgeon reported that the animal came in recently. It is reported that the animal has monthly FRONTLINE with the last application on 13 JUN 18 . Unfortunately, the cat had two ticks, one of them really large, and close to full. The veterinary surgeon further states that the cat presented on 26 JUN 2018 with ticks. The vet felt that the tick had been present for the best part of a week, was I. ricinus and fully engorged and actively feeding, so felt FRONTLINE was not working. Ticks manually removed, one approximately 48 hours presence, other vet felt longer. The animal owner reported to the MAH that the animals spend most time indoors and in a secure cat proof garden. There are no wild animals or farm animals in the area, the animal does not get bathed or go swimming, the product was not applied while the pet was wearing the collar. No people in the home are being bitten by fleas and the owner has not moved into a new home recently. |
| 29-Jun-2018 | UAE; 18UK001363; Cheshire; United Kingdom | **Species:** Feline **Breed:** Feline mixed/various breeds **Sex:** X **Sex qualifier:** Unknown **Age:** 3.00 Year(s) **Weight:** 1.814 kg* | 6 | 6 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 18-Jun-2018 | 29-Jun-2018* | 11 Day(s) | D-D | As reported by the animal owner, Henry a male domestic shorthair cat aged 7 years, Marshall a male domestic shorthair cat aged 7 years, Willow a female domestic longhair cat aged 5 years, Theo a male domestic shorthair cat aged 4 years, Sully a male domestic longhair cat aged 4 years and Toothless a male domestic shorthair cat aged 3 years, all weighing 4lbs, all of unknown reproductive status and in unknown condition were given FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown) on 18 JUN 2018 by the animal owner topically to the base of the skull for parasite control. The animal owner states that they recently purchased FRONTLINE PLUS for their cats and used it correctly from following instructions. However days later the cat (assumed cats) still have live fleas (they have seen more than 10 fleas on their cats). The animal owner states that they normally use Advantage every 6 weeks. The animal owner further states that |

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| | | | | | | | | | | | they don't know if something was wrong with the ones they purchased. The cats are inside mostly but they go out for a few hours in back yard, there are no wild animals in the area, they do not go bathing or swimming, they do not wear collars when the product is applied and no one in the home is being bitten by fleas. |
| 29-Jun-2018 | UAE; 18UK001364; -; United Kingdom | **Species:** Canine **Breed:** Mixed Breeds / various **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 28-May-2018* | N/A | D-D | As reported by the animal owner, one Shih tzu canine and one Springer Spaniel canine of unknown age, weight, sex, reproductive status and in unknown condition, were given FRONTLINE PLUS SPOT ON DOG M (batch number and expiry date unknown) on 23 JUN 2018 by the animal owner via an unknown route for parasite control. The animal owner reports that on 27 MAY 2018 they purchased two packs of FRONTLINE PLUS, one for their Shih Tzu and one for their Springer Spaniel. The staff at Pets at Home made sure they had purchased the appropriate size for the dogs. The animal owner states that they applied the pipettes, according to the instructions, on Monday 28 MAY 2018 and again on Saturday 23 JUN 2018. The animal owner states that they had stopped using FRONTLINE some years ago because it was no good for keeping fleas at bay and had gone on to Advantage, however, because they have a problem with ticks where they live, they read all the good reports for FRONTLINE PLUS and decided to try that. Although the dogs have been free of ticks for the entire period, they have never been free of fleas - even in the days after the solution has been applied. The animal owner states that every day they are combing out up to 10 fleas from both of the dogs and they are having to bath them in flea shampoo regularly. They have sprayed the house and applied flea fogger. The animal owner reports that they wont use Frontline again and will use something else. |
| 30-Jun-2018 | UAE; 18UK001365; -; United Kingdom | **Species:** Canine **Breed:** Pomeranian **Sex:** F **Sex qualifier:** Unknown **Age:** 12.00 Week(s) **Weight:** 3 - 4 kg | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 01-Jun-2017* | 27-Jun-2018* | 2 Day(s) | D-D | As reported by the animal owner, Evanna a 1 year old female Pomeranian canine weighing 4 kg, and Taya, a 12 week old female Pomeranian canine weighing 3 kg, both in unknown condition were given FRONTLINE PLUS SPOT ON DOGS S (batch number and expiry date unknown) topically between the shoulder blades on 25 JUN 2018 by the animal owner as a parasiticide. The older dog has been treated every 3 months since June 2017 and was most recently treated on 20 FEB 2018. The animal owner reports that they have used FRONTLINE PLUS SPOT ON DOGS S on both their dogs after seeing a flea on the younger of the two. After 2 days the fleas were still visible so they decided to treat the house. The animal owner reports that since using the home spray the number of fleas on the animals has decreased. 5 days after giving FRONTLINE PLUS SPOT ON both dogs are still itching and fleas are still visible. The dogs are unfortunately locked in the kitchen until they can get this issue solved. The animal owner reports that the animals spend time mainly indoors, in the back garden, local parks and the occasional beach trip. There are birds and the neighbours cat calls into the garden on a rare occasion. The animals are being bathed fortnightly. The animal owner is seeing numerous fleas on the pets, and catching between 2 and 5 each time they check, and one member of the household is being bitten on the arms. |
| 30-Jun-2018 | UAE; 18UK001366; -; United Kingdom | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products** | N/A | 30-Jun-2018* | 4 Day(s) | D-D | As reported by the animal owner, Jake a male feline of unknown age, weight, breed, reproductive status and in unknown condition was given FRONTLINE SPOT ON CAT (batch number and expiry date unknown) on 26 JUN 2018 by the animal owner via an |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | **used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | unknown route as a parasiticide. The animal owner reports that the cat has fleas. Their vets prescribed FRONTLINE. The animal owner states that they administered the FRONTLINE on Tuesday night. They are still finding fleas on Jake. The animal owner has hoovered their bed after finding a flea on the bedding. Jake was sleeping on the bed earlier on in the night. They are also treating the house with house flea spray bought from the vets, as well as hoovering the house daily and washing the pets bedding at 60 C. So far there has been no improvement for Jake. The animal owner is still combing fleas out of Jake's coat. |
| 30-Jun-2018 | UAE; 18UK001380; Somerset; United Kingdom | **Species:** Canine<br>**Breed:** French Bulldog<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 5.42 Year(s)<br>**Weight:** 10.2 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Unspecified flea shampoo;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 05-May-2018* | 23-Jun-2018 | 5 Day(s) | D-C | As reported by the attending veterinary surgeon, Daisy, a 5 year 5 month old female neutered French Bulldog canine weighing 10.2 kg and in fair condition, was administered FRONTLINE PLUS SPOT ON DOGS M (batch and expiry unknown) topically to the skin on the back of the neck by the animal owner on approximately 05 MAY 2018, 18 MAY 2018 and 18 JUN 2018 as they were seeing fleas. The animal has a history of BOAS (Brachycephalic obstructive airway syndrome). The attending vet reports that the animal owner applied an overdose of FRONTLINE PLUS SPOT ON DOG as the animal has had 3 doses in five weeks with the last one approximately 3 weeks ago. The animal owner repeatedly applied the product to the animal as they were seeing fleas. The attending vet reports that the animal owner has also used flea wash (unknown ingredients) and RIP home spray all around the house within the last weeks. On 26 JUN 2018 the animal owner reported to the attending vet that the animal had not been right since 23 JUN 2018 - subdued, trembling, intermittently off food. It was very hot on Saturday and so it was put down to this initially, but this progressed to Tuesday (26 JUN 2018). The attending vet examined the animal on 26 JUN 2018 and found muscle tremors and spasms, tense around the head and neck but with no focus of the pain, subdued, depressed and the animal was hyperaesthetic. The attending vet was concerned re meningitis and so started Prednisolone and a five day course of Clavaseptin. On 28 JUN 2018 the animal' bloods were ok but the animal was not improving. The animal owner declined referral. On 30 JUN 2018 the animal started on IVFT, treatment with Prednisolone was stopped and the animal had an injection of Dexadreson. No further medications were given. On 02 JUL 2018 the animal seemed brighter and more alert, and the muscle spasms/fasiculations had stopped and so the animal was discharged. The attending vet is not conviced at fipronil toxicity because of the time span, and as the |
| 29-Jun-2018 | UAE; 18UK001381; -; United Kingdom | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jun-2018 | 01-Jun-2018* | N/A | D-D | As reported by the animal owner, two felines of unknown age, sex, reproductive status, breed, weight and condition, were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) via an unknown route to an unknown site by the animal owner at an unknown dose on 01 JUN 2018 for an unknown indication. The animal owner reports that they haven't used the products before as they only give it when the animals need it, but that they believe that the product wasn't working. The animals spend most of the time outside, and the animal owner reports that they have wooden floors. The animal owner reports that the animals fur is falling out and they are itching due to fleas. Start date added for submission purposes only. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 08-May-2018 | UAE; 18US008595; CA; U.S.A | **Species:** Feline **Breed:** Maine Coon Cat **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 25 lbs | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 14-Feb-2018 | 28-Mar-2018* | 0 Day(s) | D-A | Suspected Adverse Event: On 8 May 2018, the owner reported the following event for Max, 14 year old, 25 pound, neutered male, Maine Coon feline.<br>28 Mar 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades.<br>Unknown date: The cat experienced intense itching, hair loss, and lethargy.<br>1 Apr 2018: The pet was presented to the clinic. The veterinarian administered an unknown oral flea preventative.<br>7 Apr 2018: The cat passed away.<br>The cat also received FRONTLINE on 7 Mar 2018 and 14 Feb 2018 but no symptoms presented. No further medical information is expected. |
| 02-Apr-2018 | UAE; 18US017118; GA; U.S.A | **Species:** Canine **Breed:** Pit Bull **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 45 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 28-Feb-2018 | 17-Mar-2018* | N/A | D-D | Suspected Adverse Event: On 2 Apr 2018 the owner reported the following event for Romeo, a 1 year old, approximately 45 pound, neutered male, Pit Bull.<br>28 Feb 2018: 1 vial of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied.<br>17 Mar 2018*: The dog started having hot spots on the dogs back and side. The owner also noticed fleas.<br>31 Mar 2018: The dog received another dose of the product.<br>The dog was not seen by a veterinarian or given any treatment.<br>The symptoms are ongoing. No further medical information expected.<br>UPDATE TO NARRATIVE 13 Apr 2018: The pet had fleas prior to applying FL. The owner was seeing a moderate amount of fleas after applying the product. She did not specify if there was a decrease in the amount of fleas after applying FL. |
| 02-Apr-2018 | UAE; 18US017318; TX; U.S.A | **Species:** Feline **Breed:** Calico **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 7 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 23-Mar-2018 | 31-Mar-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 2 Apr 2018, the owner reported the following event for Lily, 5 year old, 7 pound, spayed female, Calico feline.<br>30 Mar 2018: One vial of FRONTLINE PLUS CATS (R40202BW) was applied between the shoulder blades.<br>31 Mar 2018: The cat experienced increased itching.<br>2 Apr 2018: The symptoms are still ongoing.<br>The cat also received the product on 23 Mar 2018 and no symptoms presented. There are 2 other cats in the household that also received FRONTLINE and experienced symptoms (see cases 18US017457, and 18US017465). No further medical information is expected. |
| 02-Apr-2018 | UAE; 18US017332; OR; U.S.A | **Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | 01-Feb-2018 | 03-Mar-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 2 Apr 2018, the owner reported the following event for Donia, 4 year old, 60 pound, intact female, German Shepherd canine.<br>1 Mar 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>3 Mar 2018: The dog experienced a red inflamed areas around the |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Age:** 4.00 Year(s)<br>**Weight:** 60 lbs | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | stomach and nipples. Puss had also formed in the center of each area.<br>8 Mar 2018: The pet was presented to the clinic and diagnosed with Staph infection. The attending veterinarian prescribed Simplicef for 2 weeks.<br>22 Mar 2018: The pet recovered.<br>2 Apr 2018: Symptoms reoccurred.<br>The dog also received FRONTLINE on 1 Feb 2018 and no symptoms presented. There is one other dog in the household that did not receive the product and was asymptomatic. No further medical information is expected. |
| 02-Apr-2018 | UAE; 18US017457; TX; U.S.A | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 22 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 23-Mar-2018 | 31-Mar-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 2 Apr 2018, the owner reported the following event for Lola, 7 year old, 22 pound, spayed female, Siamese feline.<br>30 Mar 2018: One vial of FRONTLINE PLUS CATS (R40202BW) was applied between the shoulder blades.<br>31 Mar 2018: The cat experienced increased itching.<br>2 Apr 2018: The symptoms are still ongoing.<br>The cat also received the product on 23 Mar 2018 and no symptoms presented. There are 2 other cats in the household that also received FRONTLINE and experienced symptoms (see cases 18US017318, and 18US017465). No further medical information is expected. |
| 02-Apr-2018 | UAE; 18US017465; TX; U.S.A | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 23 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 23-Mar-2018 | 31-Mar-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 2 Apr 2018, the owner reported the following event for Kingster, 7 year old, 23 pound, neutered male, Siamese feline.<br>30 Mar 2018: One vial of FRONTLINE PLUS CATS (R40202BW) was applied between the shoulder blades.<br>31 Mar 2018: The cat experienced increased itching.<br>2 Apr 2018: The symptoms are still ongoing.<br>The cat also received the product on 23 Mar 2018 and no symptoms presented.There are 2 other cats in the household that also received FRONTLINE and expereinced symptoms (see cases 18US017457, and 18US017318). No further medical information is expected. |
| 03-Apr-2018 | UAE; 18US017485; MD; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 10 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous | 02-Apr-2014* | 03-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 3 Apr 2018 the owner reported the following event for Pudd, a 4 year old, approximately 10 pound, neutered male, Domestic Shorthair (Crossbreed).<br>2014*: The cat started on 1 vial of FRONTLINE PLUS CATS given to the cat topically between the shoulder blades, by the owner. The cat was treated seasonally and not consistently.<br>2 Apr 2018: The cat received another dose of the product.<br>3 Apr 2018: The owner noticed the application site is red and there is hair loss about the size of a nickel.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. The cat had vomiting before using an |

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| | | | | | | **Was the product used ok?:** Yes | | | | | unknown flea treatment. No further medical information expected. |
| 03-Apr-2018 | UAE; 18US017739; MT; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 8.2 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** IMRAB 3 TF - 1905.23; Elanco FVRCP+FeLV; **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 31-Mar-2018* | 02-Apr-2018* | 2 Day(s) | D-C | Suspected Adverse Event: On 03 Apr 2018, the veterinarian reported the following event for Lucy, a 13 year old*, 8.2 pound, spayed female Domestic Shorthair.<br>31 Mar 2018: She received an unknown FRONTLINE product (lot and expiration unknown) (unsubstantiated) one dose applied topically at an unknown location by the owner.<br>02 Apr 2018: She received an IMRAB 3 TF (18364, 17 Aug 2019) 1 mL SC in the right hind leg and an Elanco FVRCP+FeLV 1 dose SC in the left hind leg. She began experiencing lethargy and ataxia an unknown time post administration. She has not presented to the veterinary clinic. Treatments have not been initiated. Her current condition is ongoing.<br>She previously received an IMRAB 3 TF on 15 Oct 2014 with no adverse effects. She has a pertinent medical history of periodontal disease. No further medical information expected. |
| 03-Apr-2018 | UAE; 18US017798; HI; U.S.A | **Species:** Canine **Breed:** Belgian Malinois **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 110 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 31-Mar-2017* | 01-Apr-2018* | 1 Day(s) | D-D | Suspected Adverse Event: On 3 April 2018, the owner reported the following event for Lake, a 10 year old, neuterd male, 110 pound Belgian Malinois.<br>31 March 2018: One vial of FRONTLINE PLUS 89-132 LBS (P63103AR) was topically applied per label to Lake to treat fleas on his body.<br>*1 April 2018: The dog started to itch with the presence of fleas and started to pull his fur out.<br>Lake has not been seen by the vet for his ongoing symptoms. The dog has been on FL on as needed basis and has never had any previous issues. There is one other dog in the home not treated with FL. No further information available. |
| 04-Apr-2018 | UAE; 18US017845; IL; U.S.A | **Species:** Canine **Breed:** Collie **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 83 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Apr-2017* | 01-Oct-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 4 Apr 2018 the owner reported the following event for Harley, an 11 year old, 83 pound, neutered male, Collie.<br>Apr 2017*: The dog started on 1 vial of FRONTLINE PLUS DOG 45-88 LBS given to the dog topically between the shoulder blades, by the owner. The dog was treated seasonally every month. Right after the application the dog seemed restless and was pacing. The dog recovered after a few minutes. The dog had the same symptoms after each application.<br>Oct 2017*: The dog received another dose of the FRONTLINE PLUS DOG 45-88 LBS (lot unknown). The dog had the same symptoms.<br>The dog was not seen by a veterinarian or given any treatment. The dog had the same symptoms after using K9 Advantix but the symptoms lasted longer. No further medical information expected. |
| 04-Apr-2018 | UAE; 18US017876; TX; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products | 21-Mar-2018 | 21-Mar-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 4 Apr 2018, the owner reported the following event for Cleo, 2 year old, 13 pound, spayed female, Domestic Shorthair feline.<br>21 Mar 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. The cat began dry heaving. The pet ingested the product and started to whimper.<br>30 Mar 2018: The cat experienced a burn at the application site which included hair loss. The cat was not presented to the clinic |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 13 lbs | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | and no treatment was provided.<br>5 Apr 2018: Symptoms are still ongoing.<br>No further medical information is expected. |
| 04-Apr-2018 | UAE; 18US017904; KS; U.S.A | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 35 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 04-Apr-2018 | 04-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 4 Apr 2018, the owner reported the following event for Pepper, 3 year old, 35 pound, neutered male, Labrador Retriever canine.<br>4 Apr 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (R60516AL) was applied between the shoulder blades for the first time. After 1 hour the dog vomited. The pet recovered shortly after that. The pet was not presented to the clinic and no treatment was provided.<br>No further medical information is expected. |
| 04-Apr-2018 | UAE; 18US017961; MO; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Labrador, Chocolate)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Month(s)<br>**Weight:** 42 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 26-Mar-2018 | 28-Mar-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 4 Apr 2018, the owner reported the following event for Brownie, 7 month, 42 pound, spayed female, Chocolate Labrador Retriever canine.<br>26 Mar 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (R60316AL) was applied between the shoulder blades.<br>28 Mar 2018: The dog experienced skin irritation localized at the application site.<br>30 Mar 2018: The site became infected. The dog was presented to the clinic. The attending veterinarian provided wound treatment. The pet was prescribed 10 days of Cefpodoxime 100mg.<br>4 Apr 2018: The symptoms are still ongoing.<br>There is one other dog in the household that received FRONTLINE and experienced symptoms (see case 18US017973). No further medical information is expected.<br>Update 18 Apr 2018 NH: Per invoices the attending veterinarian also prescribed Neo- Predef Powder, and Carprofen. No further medical information is expected. |
| 04-Apr-2018 | UAE; 18US017973; MO; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Labrador, Chocolate)<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 7.00 Month(s)<br>**Weight:** 62 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 26-Mar-2018 | 28-Mar-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 4 Apr 2018, the owner reported the following event for Red, 7 month, 62 pound, intact male, Chocolate Labrador Retriever canine.<br>26 Mar 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R60601BR) was applied between the shoulder blades.<br>28 Mar 2018: The dog experienced skin irritation localized at the application site.<br>31 Mar 2018: The site became infected. The dog was presented to the clinic. The attending veterinarian provided wound treatment. The pet was prescribed 10 days of Cefpodoxime 100mg.<br>4 Apr 2018: The symptoms are still ongoing.<br>There is one other dog in the household that received FRONTLINE and experienced symptoms (see case 18US017961). No further medical information is expected.<br>Update 18 Apr 2018 NH: Per invoices the attending veterinarian also prescribed Carprofen. No further medical information is expected. |
| 04-Apr-2018 | UAE; 18US018074; IA; U.S.A | **Species:** Canine<br>**Breed:** Large crossbred (>20 | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 01-Mar-2010* | 14-Mar-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 4 Apr 2018, the owner reported the following event for Tucker, 8 year old, 80 pound, neutered male, Golden Retriever mix canine. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Kg)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 80 lbs | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** Prozac;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | 14 Mar 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was applied between the shoulder blades. After 1 hour the pet experienced lethargy. The pet was not presented to the clinic and no treatment was provided.<br>15 Mar 2018: The dog recovered.<br>The dog has received the product monthly since 1 Mar 2010* the same symptoms and recovery occurred after each dose. The dog has also received Prozac on a daily basis since 1 Jan 2015*. No further medical information is expected. |
| 04-Apr-2018 | UAE; 18US018105; IN; U.S.A | **Species:** Canine<br>**Breed:** Welsh Corgi<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 40 lbs | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 10-Mar-2018 | 11-Mar-2018 | 1 Day(s) | D-A | Suspected Adverse Event: On 4 Apr 2018, the owner reported the following event for a Corgi canine (all other signalments unknown).<br>10 Mar 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (R60811AL) was applied at an unknown location.<br>Unknown date: The dog experienced vomiting, anorexia, increased urinating, and increase drinking. The pet was presented to the clinic. The attending veterinarian administered B12 injection and prescribed an unknown medication.<br>22 Mar 2018*: The dog experienced anal bleeding and shortness of breath. The dog was euthanized.<br>No further medical information is expected.<br>Update 10 Apr 2018 NH: Owner called to report the event for Jack, 10 year old, 40 pound, neutered male, Welsh Corgi canine.<br>10 Mar 2018: The product was applied between the shoulder blade for the first time.<br>11 Mar 2018: The symptoms presented.<br>Update 27 Jun 2018: Upon review the route of administration in the product screen was corrected. |
| 05-Apr-2018 | UAE; 18US018130; NJ; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 11.00 Year(s)<br>**Weight:** 14 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** Unknown vaccination;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Apr-2012* | 02-Apr-2018* | 1 Day(s) | D-D | Suspected Adverse Event: On 5 Apr 2018 the owner reported the following event for Jelli, an approximately 11 year old, approximately 14 pound, neutered male, Domestic Shorthair (Crossbreed).<br>2012*: The cat started on 1 vial of FRONTLINE PLUS CATS given to the cat topically between the shoulder blades, by the owner. The owner treated every month seasonally.<br>25 Mar 2018*: The cat was given an unknown vaccination.<br>1 Apr 2018*: The cat received another dose of FRONTLINE PLUS CATS (P41401).<br>2 Apr 2018*: The cat had hair loss at the application site about ¾ of an inch wide. The skin at the application site was scaly.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. The cat previously had a neurotoxic reaction (cat was hyperactive) after using Sergeants. No further medical information expected OR No further information available at this time. |
| 06-Apr-2018 | UAE; 18US018682; NH; U.S.A | **Species:** Feline<br>**Breed:** American Shorthair<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 06-Apr-2018 | 06-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 6 April 2018, the owner reported the following event for a male American Shorthair (signalment unknown).<br>*6 April 2018: The owner applied one vial of FRONTLINE PLUS CATS (R40311AW) to the cat to the skin between the shoulder blades. Following the treatment the cat was lethargic and vomiting.<br>No further medical information available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Yes | | | | | |
| 09-Apr-2018 | UAE; 18US018893; MI; U.S.A | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 17 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; Glucosamine DS Plus; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 08-Apr-2018 | 09-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 9 Apr 2018 the owner reported the following event for Zoey, a 4 year old, 17 pound, spayed female, Shih Tzu.<br>2014*: The dog started on 1 dose of HEARTGARD PLUS (68 MCG/57 MG). The dog is treated seasonally from Apr-Nov.<br>7 Feb 2018: The dog started on Glucosamine DS Plus being treated for the spacing between her back legs being far apart.<br>7 Apr 2018: the dog was treated with another dose of Glucosamine DS Plus.<br>8 Apr 2018: The dog started on 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) given to the dog topically, between the shoulder blades, by the owner. This was the first dose applied. The dog also received another dose of HEARTGARD PLUS (68 MCG/57 MG) (7BC0191, 28 Feb 2020).<br>9 Apr 2018: The dog vomited bile. The dog has not been seen by a veterinarian or given any treatment. The symptoms are ongoing.<br>No further medical information expected. |
| 09-Apr-2018 | UAE; 18US018965; CT; U.S.A | **Species:** Canine **Breed:** Beagle **Sex:** F **Sex qualifier:** - **Age:** - **Weight:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 08-Apr-2018 | 08-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 9 Apr 2018, the owner reported the following event for Buster, male, Hound canine (all other signalments unknown).<br>8 Apr 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>9 Apr 2018*: The dog experienced strange behavior and inability to move his leg. The pet also experienced neurological symptoms which included shaking and walking in circles. The owner bathed the pet. It is unknown if the pet was presented to the clinic. The status of the pet is unknown.<br>There is 1 other dog in the household that received FRONTLINE and also experienced symptoms (see case 18US019413). No further medical information is expected.<br>Update 11 Apr 2018 NH: The owner reported the following event for Buster, 11 month old, 75 pound, neutered male, Hound canine.<br>8 Apr 2018: The dog experienced symptoms after 1-2 hours. The pet was not presented to the clinic. The pet stopped shaking after the owner administered a bath. The strange behavior continued.<br>9 Apr 2018: The dog recovered. |
| 09-Apr-2018 | UAE; 18US018997; CA; U.S.A | **Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 25-Mar-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 9 Apr 2018, the owner reported the following event for a Jack Russell Terrier canine (all other signalment unknown).<br>25 Mar 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P61522AL) was applied at an unknown location.<br>Unknown date: The dog experienced vomiting. The pet was not presented to the clinic. The current status of the pet is unknown.<br>No further medical information is expected. |
| 10-Apr-2018 | UAE; 18US019109; -; U.S.A | **Species:** Canine **Breed:** Canine (unknown) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 08-Apr-2018* | 08-Apr-2018 | 0 Day(s) | D-B | Suspected Adverse Event:The following was reported by a pet owner on a social media website for Ryan, an unknown breed, female canine. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | 7 April 2018: The dog received an unknown dosage of FRONTLINE PLUS (product unsubstantiated, lot number unknown).<br>8 April 2018: The pet owner reported that the dog was immobile, couldn't move her hind legs, and had vision impairment with dilated pupils. It was also reported that the dog was hypersalivating, would not eat or drink, was panicked, and seemed to be in a in state of confusion. It is unknown if this pet had had this product in the past, it is unknown if this pet had any concurrent medical conditions, and it is unknown of this pet owner sought veterinary care for this pet. No other medical information is expected. |
| 10-Apr-2018 | UAE; 18US019134; NM; U.S.A | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 90 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Apr-2016* | 01-Apr-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 10 Apr 2018 the veterinarian reported the following event for P-boy, a 3 year old, 90 pound, neutered male, Retriever Labrador.<br>2016*: The dog started on 1 vial of FRONTLINE PLUS given to the dog topically (unknown application site) by the owner. The dog was treated monthly on a seasonal basis.<br>1 Apr 2018: The dog received another dose of FRONTLINE PLUS (lot unknown, product unsubstantiated). The dog was immediately itchy and had some red skin at the application site which only lasted 24 hours.<br>2 Apr 2018: 36 hours after the application, the dog started dry heaving and experienced ataxia. The dog recovered after a few seconds.<br>The dog was seen by the veterinarian but was not given any treatment. The dog has a pre-existing heart murmur. No further medical information expected. |
| 10-Apr-2018 | UAE; 18US019164; CA; U.S.A | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 12.5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 28-Feb-2018 | 27-Mar-2018* | 27 Day(s) | D-D | Suspected Adverse Event: On 10 Apr 2018 the owner reported the following event for Beau, a 4 year old, 12.5 pound, neutered male, Shih Tzu.<br>28 Feb 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60509AL) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied. The dog had a few fleas before the first dose.<br>27 Mar 2018*: The dog started itching and the owner saw more fleas.<br>29 Mar 2018: The owner applied another dose of the product.<br>The dog was seen by the veterinarian but was not given any treatment. The symptoms are ongoing. No further medical information expected. |
| 10-Apr-2018 | UAE; 18US019220; CT; U.S.A | **Species:** Canine<br>**Breed:** Terrier (Jack Russell)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 12.00 Year(s)<br>**Weight:** 16 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2017 | 02-Jan-2017* | 1 Day(s) | D-D | Suspected Adverse Event: On 6 Apr 2018, the owner reported the following event for Nellie, 12 year old, 16 pound, spayed female, Jack Russell Terrier canine.<br>Unknown date: One vial of FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) was applied between the shoulder blades. After 24 hours the dog experienced lethargy and anorexia. The pet recovered after 24 hours. The pet was not presented to the clinic and no treatment was provided.<br>The pet also received NEXGARD and experienced symptoms (see case 18US018594). No further medical information is expected. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 10-Apr-2018 | UAE; 18US019317; MI; U.S.A | **Species:** Canine **Breed:** Boston Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 25 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 136MCG/326MG ; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Apr-2018* | 01-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 10 Apr 2018, a pet owner reported the following event for Lucy, a 3 year old, 25 pound, spayed female, Boston Terrier. UNKNOWN DATES: The owner reported that when she gives a dose of HEARTGARD PLUS (136 MCG/114 MG) (lot number and expiration date unknown) and FRONTLINE PLUS DOG 23-44 LBS (lot number unknown), the dog has loose stool and hides. No further medical information expected. |
| 10-Apr-2018 | UAE; 18US019410; GA; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.50 Year(s) **Weight:** 12 lbs | 4 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 08-Mar-2018 | 19-Mar-2018* | 11 Day(s) | D-D | Suspected Adverse Event: On 10 Apr 2018 the owner reported the following event for an unknown feline (all other signalments unknown). 8 Mar 2018: An unknown amount of FRONTLINE PLUS CATS (P41102AX) was given to the cat topically (unknown site of application), by the owner. It is unknown if this was the first dose applied. 19 Mar 2018*: The cat had a scab at the application site and the fur was missing. It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected. UPDATE 17 Apr 2018: The owner reported the following for Brapp, an approximately 1.5 year old, approximately 12 pound, neutered male. 8 Mar 2018: 1 dose of the product was given to the cat topically between the shoulder blades. This was the first dose applied. The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected. |
| 09-Apr-2018 | UAE; 18US019413; CT; U.S.A | **Species:** Canine **Breed:** Mixed Breeds / various **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Month(s) **Weight:** 35 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 08-Apr-2018 | 09-Apr-2018* | 1 Day(s) | D-D | Suspected Adverse Event: On 10 Apr 2018, the owner reported the following event for Lucy a canine (all other signalments unknown). 8 Apr 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was applied between the shoulder blades. 9 Apr 2018*: The dog experienced anorexia. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown. There is one other dog in the household that also received FRONTLINE and experienced symptoms (see case 18US018965). No further medical information is expected. Update 11 Apr 2018 NH: The owner reported the following event for Lucy, 11 month old, 35 pound, spayed female, Mixed breed canine. 9 Apr 2018: The dog experienced symptoms and was presented to the clinic. No treatment was provided. The dog recovered after a few hours. |
| 10-Apr-2018 | UAE; 18US019426; | **Species:** Canine **Breed:** Doberman | 1 | 1 | 0 | **Product used:** FIPRONIL | N/A | 24-Mar-2018 | 4 Day(s) | D-C | Suspected Adverse Event: On 10 Apr 2018, the owner reported the following event for Bruta, 10 year old, 64 pound, intact male, |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | MI; U.S.A | **Sex:** M<br>**Sex qualifier:** -<br>**Age:** 10.00 Year(s)<br>**Weight:** 64 lbs | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | Doberman canine.<br>20 Mar 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>24 Mar 2018: The dog experienced uncoordinated movement. The pet also experienced lethargy.<br>26 Mar 2018: The dog was presented to the clinic. The attending veterinarian prescribed a oral steroid and pain medication.<br>10 Apr 2018: Symptoms are still ongoing.<br>The dog receive FRONTLINE on a prior unknown date and no symptoms presented. No further medical information is expected. |
| 11-Apr-2018 | UAE; 18US019442; NY; U.S.A | **Species:** Canine<br>**Breed:** Pomeranian<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 14.00 Year(s)<br>**Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Unknown herbal medications; Deramaxx;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 07-Apr-2004* | 08-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 12 Apr 2018 the owner reported the following event for Bugzy, an approximately 14 year old, approximately 10 pound, neutered male, Pomeranian.<br>2004*: The dog started on 1 vial of FRONTLINE PLUS DOG 5-22 LBS given to the dog topically between the shoulder blades, by the owner. The dog is treated monthly on a seasonal basis usually Mar-Aug.<br>Jan 2018*: The dog started on 2 unknown herbal medications and Deramaxx to treat h1 tracheobronchitis and h39 spinal disease.<br>5 Apr 2018: The dog received the most recent dose of Deramaxx.<br>7 Apr 2018: The dog received the most recent dose of FRONTLINE PLUS DOG 5-22 LBS (M62902AL).<br>8 Apr 2018: The dog received the most recent doses of the unknown herbal medications. The dog started scratching.<br>The dog was not seen by a veterinarian or given any treatment.<br>The symptoms are ongoing. No further medical information expected. |
| 11-Apr-2018 | UAE; 18US019444; MA; U.S.A | **Species:** Canine<br>**Breed:** Pomeranian<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 15 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 08-Apr-2015* | 08-Apr-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 11 April 2018, the owner reported the following event for Sophie, a 5 year old, 15 pound, spayed female Pomeranian/ Chihuahua mix.<br>8 April 2018: One vial of FRONTLINE PLUS DOG 5-22 (FL) (lot unknown) was topically applied to the dog. Immediately after the treatment the dog was itching,and she had tremors.<br>9 April 2018: The dog would just stand there with her tail between her legs and she was not herself<br>10 April 2018: The dog started vomiting and squinting her eyes.<br>11 April 2018: The dog was taken to the vet, no treatment had been given at the time.<br>The dog has been on FL seasonally over the course of 3 years and she had past reaction of itching and behavior change. There is one other dog in the home who did not have a reaction. No further medical information available. |
| 11-Apr-2018 | UAE; 18US019535; IL; U.S.A | **Species:** Canine<br>**Breed:** Hound Breeds (200 Series)<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 1.00 Year(s)<br>**Weight:** 72 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No | 10-Mar-2018 | 10-Mar-2018* | N/A | D-D | Suspected Adverse Event: On 11 Apr 2018, the owner reported the following event for Henry, 1 year old, 72 pound, intact male, Hound mix canine.<br>10 Mar 2018: One vial of FRONLTINE PLUS DOG 45-88 LBS (R61201BR) was applied between the shoulder blades.<br>Unknown date: The dog experienced intense itching and biting on the lower back.<br>5 Apr 2018: Another vial was applied. The pet experienced bleeding around the lower back.<br>11 Apr 2018: symptoms are still ongoing.<br>No further medical information is expected. |

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| | | | | | | (Treatment / vaccination program not respected) | | | | | |
| 11-Apr-2018 | UAE; 18US019573; MN; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 96 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 05-Apr-2018 | 2 Day(s) | D-C | Suspected Adverse Event: On 11 Apr 2018 the veterinarian reported the following event for Ruger, a 6 year old, 96 pound, neutered male, canine (all other signalments unknown).<br>3 Apr 2018: 1 vial of FRONTLINE (lot unknown, product unsubstantiated) was given to the dog topically (application site unknown), by the owner. The dog has been on the product before, but for an unknown amount of time.<br>5 Apr 2018: The dog had a seizure. The dog laid on its side and the legs stiffed up. The dog was whimpering. The seizure lasted about 2 minutes.<br>The dog was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 11-Apr-2018 | UAE; 18US019587; CA; U.S.A | **Species:** Canine **Breed:** Spaniel (English Springer) **Sex:** M **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 55 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Prednisone; Glucosamine; Ketoconazole; **Route:** unknown **Was the product used ok?:** Unknown to Company | 08-Apr-2004* | 08-Apr-2018 | 0 Day(s) | D-B | Suspected Adverse Event: On 11 Apr 2018 the owner reported the following event for a Spaniel (English Springer) (all other signalments unknown).<br>Mar 2018*: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (P61201AR) was given to the dog (unknown route and site of application), by the owner. It is unknown if this was the first application. Later that day, the dog could not get up. The dog had paralysis in the back legs. The dog was crying.<br>8 Apr 2018: The dog received another dose of the product. The dog had the same symptoms but more severe.<br>The dog was seen by the veterinarian but it is unknown if any treatment was given. The symptoms are ongoing. No further medical information expected.<br>UPDATE 13 Apr 2018: The owner reported the following for Buster, a 14 year old, 55 pound, neutered male.<br>2004*: The dog started on 1 vial of FRONTLINE PLUS DOG 45-88 LBS. The dog was not treated regularly but was treated on and off throughout the years. The dog also started on Prednisone and Ketoconazole for allergies.<br>Aug 2017*: The dog started on Glucosamine for arthritis.<br>7 Apr 2018: The dog received a dose of Prednisone, Glucosamine, and Ketoconazole.<br>The dog was not given any treatment by the veterinarian. No further medical information expected. |
| 11-Apr-2018 | UAE; 18US019661; CA; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 14 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | 10-Apr-2018 | 11-Apr-2018 | 1 Day(s) | D-C | Suspected Adverse Event: On 11 April 2018, the owner reported the following event for Honey Bee, a 14 pound, 10 year old, spayed female Chihuahua.<br>10 April 2018, 2/3 vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied to Honey Bee for the first time.<br>11 April 2018: The dog's jaws and cheeks were swollen shut and the dog was lethargic.<br>The dog has not been seen by the vet. There is one other dog in the home who did not have a reaction. No further medical information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 11-Apr-2018 | UAE; 18US019761; DC; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Jan-2018* | 01-Jan-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 11 Apr 2018 the owner reported the following event for an unknown feline (all signalments unknown). Unknown date: An unknown amount of FRONTLINE PLUS CATS (lot unknown) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. Sometime after the application, the cat started drooling. It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected. |
| 12-Apr-2018 | UAE; 18US020010; WA; U.S.A | **Species:** Canine **Breed:** Dachshund (Miniature) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 11-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 12 Apr 2018, the owner reported the following event for Flynn, Dachshund canine (all other signalments unknown). 11 Apr 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P62719AL) was applied at an unknown location. The dog began shaking their head and experienced hyperactivity. It is unknown if the pet was presented to the clinic or if any treatment was provided. The current status of the pet is unknown. No further medical information is expected. |
| 12-Apr-2018 | UAE; 18US020045; PA; U.S.A | **Species:** Canine **Breed:** Havanese **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 10 lbs | 4 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 12-Jan-2018 | 12-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 12 Apr 2018, the owner reported the following event for Lucy, 1 year old, 10 pound, spayed female, Havenese canine. 12 Apr 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P62719AL) was applied between the shoulder blades. After a few hours the dog vomited and started shaking. The pet was not presented to the clinic and the owner bathed the dog. Symptoms are still ongoing. The dog also received FRONTLINE on 12 Jan 2018 and no symptoms presented. There are 4 other dogs in the household that also received FRONTLINE and are asymptomatic. No further medical information is expected. |
| 12-Apr-2018 | UAE; 18US020048; WA; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 02-Apr-2018 | 02-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 12 Apr 2018, the owner reported the following event for Skipper, 1 year old, neutered male, Domestic Shorthair feline (all other signalments unknown). 2 Apr 2018: One vial of FRONTLINE PLUS CATS (R40801AW) was applied at a unknown location. Unknown date: The cat experienced a cough and was making squeaky noises. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown. No further medical information is expected. |
| 12-Apr-2018 | UAE; 18US020068; | **Species:** Canine **Breed:** Retriever | 2 | 1 | 0 | **Product used:** FIPRONIL | 02-Apr-2010* | 06-Apr-2018 | 4 Day(s) | D-D | Suspected Adverse Event: On 12 Apr 2018, the owner reported the following event for Shelby, 8 year old, 70 pound, spayed |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | -; U.S.A | (Golden)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 70 lbs | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | female, Golden Retriever Poodle mix canine.<br>2 Apr 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61811AR) was applied between the shoulder blades down to the base of the tail.<br>6 Apr 2018: The dog experienced sores around the paw and elbow region.<br>8 Apr 2018: The dog also experienced sores around application site.<br>9 Apr 2018: The dog was presented to the clinic. The attending veterinarian prescribed Synotic Alus, a topical antibiotic, medicated shampoo, and Benadryl.<br>13 Apr 2018: Symptoms improved but they are still ongoing.<br>The dog has received FRONTLINE monthly since 2 Apr 2010* and no symptoms presented. There is one other dog in the household that also received the product and is asymptomatic. No further medical information is expected. |
| 12-Apr-2018 | UAE; 18US020115; CA; U.S.A | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 11-Apr-2018 | 11-Apr-2018 | 1 Hour(s) | D-D | Suspected Adverse Event: On 12 Apr 2018 the owner reported the following event for a Yorkshire Terrier (all other signalments unknown).<br>11 Apr 2018: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was given to the dog (unknown route and site of application), by the owner. This was the first dose applied. Approximately 30 minutes-1 hour later, the dog vomited and was lethargic. The dog curled up into a ball and was shaking. The dog also had a lack of appetite.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected. |
| 13-Apr-2018 | UAE; 18US020147; FL; U.S.A | **Species:** Canine<br>**Breed:** Cockapoo<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 30 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Feb-2018* | 01-Feb-2018* | N/A | D-D | Suspected Adverse Event: On 13 Apr 2018 the owner reported the following event for Pedro, a 3 year old, approximately 30 pound, neutered male, Cockapoo.<br>Feb 2018*: 1 vial of FRONTLINE PLUS DOG 23-44 LBS (R61020FL) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied. On an unknown date after the application, the dog started scratching. The owner did not see any flea activity. The scratching was continuous throughout the entire month.<br>Mar 2018*: The dog received another dose of the product. The scratching increased.<br>The dog was seen by the veterinarian but was not given any treatment. The symptoms are ongoing. No further medical information expected. |
| 13-Apr-2018 | UAE; 18US020299; CA; U.S.A | **Species:** Canine<br>**Breed:** Shepherd Dog (Others)<br>**Sex:** F<br>**Sex qualifier:** Lactating<br>**Age:** 9.00 Month(s)<br>**Weight:** 48 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 16-Mar-2018 | 16-Mar-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 13 Apr 2018, the owner reported the following event for Mocha, 9 month old, 48 pound, intact female, Shepherd canine.<br>16 Mar 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was applied between the shoulder blades.<br>16 Mar 2018: The pet experienced anorexia. The pet was not presented to the clinic and no treatment was provided.<br>20 Mar 2018: The dog recovered.<br>No further medical information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 13-Apr-2018 | UAE; 18US020394; IL; U.S.A | **Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** - **Age:** 6.00 Month(s) **Weight:** 9 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 11-Apr-2018 | 11-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 13 Apr 2018 the owner reported the following event for Lulu, a 6 month old, 9 pound, non-pregnant non-lactating intact female, Maltese/Poodle (Miniature).<br>9 Apr 2018: 1 dose of HEARTGARD PLUS (68 MCG/57 MG) (lot unknown, expiration unknown) was given to the dog orally, by the owner. This was the first dose administered.<br>11 Apr 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (P61522AL) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied. The dog started scratching, crying, and rubbing up against walls. Later the dog was hiding.<br>13 Apr 2018: The dog recovered.<br>The dog was seen by the veterinarian and given fluids. The owner gave the dog a bath. No further medical information expected.<br>UPDATE 11 JUN 2018: After internal review for DER, Local assessment agency was changed to FDA to ensure correct reportability to agency. |
| 13-Apr-2018 | UAE; 18US020444; TX; U.S.A | **Species:** Canine **Breed:** Schnauzer **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 32.5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 136MCG/326MG ; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 05-Aug-2013* | 06-Sep-2016* | 1 Day(s) | D-D | Suspected Adverse Event: On 13 April 2018, the owner reported the following event, for Feona, a 6 year old, 32.5 pound, spayed female Schnauzer.<br>*5 September 2016: One vial of FRONTLINE PLUS FOR DOGS 23-44 LBS (lot unknown) was topically applied per the label instructions.<br>*6 September 2016: The dog started to itch without the presence of fleas.<br>*7 September 2016: The dog recovered without vet assistance.<br>The dog has had FL as needed since 2013, and had similar symptoms in the past. The dog has also had issues with FRONTLINE TRITAK FOR DOGS M (2502K12) in the past. See case 18US020268. The dog also takes HEARTGARD PLUS (136 MCG/114 MG) (lot and expiration date unknown) monthly all her life with no issues. No further medical information expected.<br>UPDATE 11 JUN 2018: After internal review for DER, Local assessment agency was changed to FDA to ensure correct reportability to agency. |
| 16-Apr-2018 | UAE; 18US020566; TX; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 11-Apr-2017* | 11-Jun-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 16 Apr 2018 the owner reported the following event for a Chihuahua (all other signalments unknown).<br>4 Jun 2014*: The dog started on HEARTGARD (lot unknown, expiration unknown, product unsubstantiated) given to the dog orally by the owner. The dog was treated monthly on a year round basis.<br>4 Apr 2017*: The dog was given another dose of HEARTGARD.<br>11 Apr 2017*: The dog started on 1 vial of FRONTLINE (lot unknown, product unsubstantiated) given to the dog topically, between the shoulder blades, by the owner. The dog was treated once a month. The dog was restless and hyper. The dog vomited and had a lack of appetite. The symptoms lasted about 3 days. The dog had the same symptoms each time the product was given.<br>4 Jun 2017*: The dog was given another dose of HEARTGARD.<br>11 Jun 2017*: The dog was given the last dose of FRONTLINE. The dog had the same symptoms.<br>14 Jun 2017*: The dog recovered.<br>The dog was seen by a veterinarian but was not given any treatment. No further medical information expected.<br>UPDATE 11 JUN 2018: After internal review for DER, Local |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | assessment agency was changed to FDA to ensure correct reportability to agency. |
| 16-Apr-2018 | UAE; 18US020754; MD; U.S.A | **Species:** Feline **Breed:** American Shorthair **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 13 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 12-Apr-2014* | 13-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 16 Apr 2018 the owner reported the following event for a female, American Shorthair (all other signalments unknown).<br>12 Apr 2018: An unknown amount of FRONTLINE PLUS CATS (lot unknown) was given to the cat (unknown route and site of application), by the owner. The cat has been on the product for an unknown amount of time. On an unknown date after the application the cat had a white spot and the cat started losing fur at the application site.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected.<br>UPDATE 20 Apr 2018: The owner reported the following for Lily, an approximately 6 year old, approximately 13 pound, spayed female.<br>2014*: The cat started on FRONTLINE PLUS CATS.<br>12 Apr 2018: Cat received 1 vial of the product topically, between the shoulder blades.<br>13 Apr 2018: The owner noticed the skin at the application site was dry and white. The fur started to fall out in that area.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected. |
| 16-Apr-2018 | UAE; 18US020783; IL; U.S.A | **Species:** Canine **Breed:** Rottweiler **Sex:** M **Sex qualifier:** - **Age:** 11.00 Year(s) **Weight:** 80 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 14-Apr-2018 | 14-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 16 Apr 2018 the owner reported the following event for Tyson, an 11 year old, approximately 80 pound, intact male, Rottweiler.<br>14 Apr 2018: 1 vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied.<br>Approximataly 6 hours after the application, the dog vomited and became lethargic.<br>The dog was not seen by a veterinarian or given any treatment.<br>The symptoms are ongoing. No further medical information expected. |
| 17-Apr-2018 | UAE; 18US020884; CA; U.S.A | **Species:** Feline **Breed:** Manx **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 17-Apr-2018* | 17-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 17 April 2018, the owner reported the following event for Mikey, a male Manx (further signalment unknown).<br>*17 April 2018: One vial of FRONTLINE PLUS CATS (D4020AL) was topically applied to Mikey on an unknown date.<br>Following the treatment the cat is scratching abnormally, chewing his legs, and removing his fur. No further information available. |
| 17-Apr-2018 | UAE; 18US020978; CA; U.S.A | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | 06-Apr-2017 | 08-Apr-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 17 Apr 2018, the owner reported the following event for Scooter, 12 year old, 11 pound, neutered male, Shih Tzu canine.<br>6 Apr 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Neutered<br>**Age:** 12.00 Year(s)<br>**Weight:** 11 lbs | | | | 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | (R60830AL) was applied between the shoulder blades.<br>8 Apr 2018: The dog experienced intense itching. The pet was not presented to the clinic and no treatment was administered.<br>17 Apr 2018: Symptoms are still ongoing.<br>The pet has received FRONTLINE since 6 Apr 2017 and no symptoms presented. No further medical information is expected. |
| 17-Apr-2018 | UAE; 18US020992; CA; U.S.A | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 2.00 Year(s)<br>**Weight:** 12 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Low dose) | 04-Feb-2018 | 04-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 17 April 2018, the owner reported the following event for Dahlia, a 2 year old, 12 pound spayed female Poodle (miniature).<br>On 4 April 2018: A half vial of FRONTLINE PLUS DOG 5-22 LBS (FL) (R604521AL) was topically applied to the dog and 10-12 hours later the dog started pacing, walking with her tail down, and salivating.<br>5 April 2018: The dog recovered without vet assistance.<br>The dog has been treated with a half of dose of FL monthly since Jan and the dog has the same reaction each time. There is one other treated dog in the home who didn't have an issue. No further medical information expected. |
| 17-Apr-2018 | UAE; 18US021084; OR; U.S.A | **Species:** Canine<br>**Breed:** German Shepherd Dog<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 1.00 Year(s)<br>**Weight:** 93 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 05-Feb-2018 | 19-Feb-2018* | 2 Week(s) | D-D | Suspected Adverse Event: On 17 Apr 2018, the owner reported the following event for Pala, 1 year old, 93 pound, spayed female, German Shepherd mix canine.<br>5 Feb 2018: One vial of FRONTLINE PLUS DOG 89-132 LBS (R60908AR) was applied between the shoulder blades.<br>19 Feb 2018*: The dog experienced hair loss throughout the entire body excluding the ears. A rash developed on the stomach and sides. The pet also experienced loose stool.<br>Unknown date: The pet was presented to the clinic but no treatment was provided.<br>17 Apr 2018: The pet recovered.<br>No further medical information is expected. |
| 17-Apr-2018 | UAE; 18US021112; IN; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 11.00 Month(s)<br>**Weight:** 12 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** Revolution;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Oct-2017 | 17-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 17 Apr 2018 the owner reported the following event for Manu, an 11 month old, 12 pound, neutered male, Domestic Shorthair (Crossbreed).<br>Oct 2017*: The cat received 1 dose of FRONTLINE PLUS CATS. The cat also started on 1 dose of Revolution. The cat was treated with only Revolution on a year round basis.<br>17 Apr 2018: 1 vial of FRONTLINE PLUS CATS (P40203AW) was given to the cat topically, between the shoulder blades, by the owner. The cat also received a dose of Revolution. The cat licked the product and started foaming at the mouth. The owner bathed the pet and the symptoms stopped.<br>The cat was seen by the veterinarian but was not given any treatment. No further medical information expected. |
| 18-Apr-2018 | UAE; 18US021178; NY; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Labrador, Yellow)<br>**Sex:** M<br>**Sex qualifier:** Neutered | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products** | 16-Apr-2018 | 17-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 18 April 2018, the owner reported the following event for Cody, a 11 year old, 96 pound, neutered male Retriever (Labrador, Yellow).<br>16 April 2018: One vial of FRONTLINE PLUS DOG 89-132 LBS (J63804AL) was applied to Cody per label for the first time.<br>17 April 2018: The dog developed a chemical burn at the |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Age:** 11.00 Year(s)<br>**Weight:** 96 lbs | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | application site that was swollen, red, and oozing blood.<br>The dog has not been seen by the vet for his ongoing symptoms, but the owner washed the area with cool water. No further medical information expected. |
| 18-Apr-2018 | UAE; 18US021201; IA; U.S.A | **Species:** Canine<br>**Breed:** Bichon Frise<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Month(s)<br>**Weight:** 9 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Low dose) | 31-Aug-2017* | 01-Oct-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 18 Apr 2018, the owner reported the following event for Rigley, 10 month, 9 pound, neutered male, Bichon Frise canine.<br>Oct 2017*: Half a vial of FRONTLINE PLUS DOG 5-22 LBS (R60308AL) was applied between the shoulder blades. After a few hours the dog experienced lethargy. The pet was not presented to the clinic. The owner administered Benadryl.<br>Unknown date: The pet recovered.<br>The pet received FRONLTINE monthly since 31 Aug 2017* and no symptoms presented. No further medical information is expected. |
| 18-Apr-2018 | UAE; 18US021298; CA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 16.00 Year(s)<br>**Weight:** 10 lbs | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 13-Apr-2018 | 14-Apr-2018 | 1 Day(s) | D-C | Suspected Adverse Event: On 18 Apr 2018 the owner reported the following event for Brak, a 16 year old, approximately 10 pound, neutered male, feline (unknown).<br>13 Apr 2018: 1 vial of FRONTLINE PLUS CATS (lot unknown) was given to the cat, topically between the shoulder blades, by the owner. This was the first dose applied.<br>14 Apr 2018: The cat was lethargic. The back legs were weak and the cat could not stand. The legs started to get better but the cat was limping, staring into space and running around erratically. The cat was pushing around its food and laying down in abnormal places. The cat was itching, vomited, and had weight loss.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. The cat has had skin sensitivity and excess vomiting after using Cheristin before. No further medical information expected. |
| 18-Apr-2018 | UAE; 18US021339; CA; U.S.A | **Species:** Canine<br>**Breed:** Pointer (German Short-Haired)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 48 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2016 | 01-Jan-2016* | 0 Day(s) | D-D | Suspected Adverse Event: On 18 Apr 2018, the owner reported the following event for Lele, 10 year old, 48 pound, spayed female, German Shorthair Pointer canine.<br>Unknown date: One vial of FRONTLINE PLUS DOG 45-88 LBS (M62707AR) was applied between the shoulder blades.<br>Immediately after the dog began running around in circles like the product was burning. The pet was not presented to clinic and no treatment was provided. The dog recovered after a few minutes.<br>There is one other dog in the household that also experienced symptoms after using the FRONTLINE (see case 18US021343).<br>No further medical information is expected. |
| 18-Apr-2018 | UAE; 18US021343; CA; U.S.A | **Species:** Canine<br>**Breed:** Pointer (German Short-Haired)<br>**Sex:** M<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products** | 01-Jan-2016* | 01-Jan-2016* | 0 Day(s) | D-D | Suspected Adverse Event: On 18 Apr 2018, the owner reported the following event for Gunther, 8 year old, 58 pound, neutered male, German Shorthair Pointer canine.<br>Unknown date: One vial of FRONTLINE PLUS DOG 45-88 LBS (M62707AR) was applied between the shoulder blades.<br>Immediately after the dog began running around in circles like the |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 58 lbs | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | product was burning. The pet was not presented to clinic and no treatment was provided. The dog recovered after a few minutes. There is one other dog in the household that also experienced symptoms after using the FRONTLINE (see case 18US021339). No further medical information is expected. |
| 18-Apr-2018 | UAE; 18US021476; NJ; U.S.A | **Species:** Canine<br>**Breed:** Mixed Breeds / various<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 2.00 Year(s)<br>**Weight:** 26 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 136MCG/326MG ;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 14-Apr-2017 | 15-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 18 April 2018, the owner reported the following event for Basil, a 2 year old 26 pound, spayed female mixed breed dog.<br>25 March 2018: One chew of HEARTGARD PLUS (136 MCG/114 MG) (6BC0724, Nov 2019) was orally administered to the dog.<br>14 April 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (FL) (lot unknown) was topically applied per label to Basil.<br>15 April 2018: The dog was lethargic, vomiting, dry heaving, and had a loss of appetite.<br>The dog has not been seen by the vet for her ongoing symptoms. The dog has been on FL seasonally over the course of a year and has had these symptoms each time where she would recover in a few days. The dog has been on HG year round with no issues. No further medical information expected.<br>UPDATE 11 JUN 2018: After internal review for DER, Local assessment agency was changed to FDA to ensure correct reportability to agency. |
| 18-Apr-2018 | UAE; 18US021479; CA; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 18-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 18 Apr 2018, the owner reported the following event for a canine (all other signalments unknown). Unknown date: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was applied between the shoulder blades. The pet experienced itching. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the dog is unknown.<br>No further medical information is expected. |
| 19-Apr-2018 | UAE; 18US021501; DE; U.S.A | **Species:** Canine<br>**Breed:** Great Dane<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 18-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 19 Apr 2018, the owner reported the following event for a Great Dane canine (all other signalment unknown).<br>17 Apr 2018: One vial of FRONTLINE PLUS DOG 89-132 LBS (R60908DR) was applied between the shoulder blades.<br>18 Apr 2018: The dog experienced difficulty getting up and walking. The pet also experienced lethargy and anorexia. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the dog is unknown.<br>The dog also received FRONTLINE in the past on an unknown date. The pet experienced the same symptoms. No further medical information is expected. |
| 19-Apr-2018 | UAE; 18US021516; MO; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Labrador, Chocolate) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | 12-Apr-2018* | 15-Apr-2018 | 3 Day(s) | D-C | Suspected Adverse Event: On 19 Apr 2018, the veterinarian reported the following event for Sam, a 7 year old (born 11 Jan 2011), 80.5 pound, neutered male Chocolate Labrador Retriever.<br>9 Apr 2018: The dog was vaccinated with RECOMBITEK C8 |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 80.5 lbs | | | | 9% SPOT ON<br>**Other products used:** RECOMBITEK C8 - 47K9.R0;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | (45546B49041, 17 Feb 2019), 1 mL, SC, intrascapular.<br>15 Apr 2018: The pet owner reported a lump between the shoulder blades. The dog presented to the clinic with a firm, round, non-tender, plum-sized mass at the injection site. The dog was treated with Benadryl and his current health status is unknown.<br>No further medical information is available at this time.<br>UPDATE 22 May 2018: Per received medical records, the dog had FRONTLINE PLUS DOG 45-88 LBS (product unsubstantiated) appllied intrascapular on 12 Apr 2018. No further medical information is expected |
| 19-Apr-2018 | UAE; 18US021521; PA; U.S.A | **Species:** Canine<br>**Breed:** St. Bernard<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 3.00 Year(s)<br>**Weight:** 175 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Low dose) | 12-Apr-2018* | 13-Apr-2018* | 1 Day(s) | D-C | Suspected Adverse Event: On 19 Apr 2018, a veterinarian reported the following event for Teddy Bear, a 3 year old (25 Jan 2015), 175 pound, intact male St. Bernard.<br>12 Apr 2018*: The dog was applied 1 vial of FRONTLINE PLUS DOG (Unsubstantiated) (lot and expiration unknown) in an unknown location.<br>13 Apr 2018*: The dog had a seizure that lasted 3 to 4 minutes, and then recovered.<br>Teddy Bear has a history of septic arthritis since Feb 2018.<br>19 Apr 2018: The dog presented to the clinic and blood work was performed, but no results at the time of report.<br>No further medical information expected.<br>Update 19 Apr 2018 NH: Owner called to report 1 vial of FRONTLINE PLUS 89-132 (R60402) was applied to the dog. |
| 19-Apr-2018 | UAE; 18US021616; MI; U.S.A | **Species:** Canine<br>**Breed:** Boston Terrier<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 32 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 09-Apr-2010* | 11-Apr-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 19 Apr 2018, the owner reported the following event for Pepe Le'pew, 6 year old, 32 pound neutered male, Boston Terrier canine.<br>9 Apr 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (P16014AI) was applied between the shoulder blades.<br>11 Apr 2018: The dog experienced intense itching. The pet was not presented to the clinic and the owner administered Benadryl.<br>19 Apr 2018: The symptoms are still ongoing.<br>The dog has received the FRONTLINE monthly since 9 Apr 2010* and no symptoms presented. No further medical information is expected. |
| 19-Apr-2018 | UAE; 18US021653; FL; U.S.A | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Month(s)<br>**Weight:** 2 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 17-Apr-2018 | 18-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 19 Apr 2019 the owner reported the following event for Jasper, an approximately 4 month old, approximately 2 pound, spayed female, Siamese.<br>16 Apr 2018: 1 vial of FRONTLINE PLUS CATS (R50115AW) was given to the cat topically, between the shoulder blades, by the owner. This was the first dose applied.<br>17 Apr 2018: The cat was lethargic.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected.<br>UPDATE 25 Apr 2018: After receiving invoice, verified owner purchased product and applied on 17 Apr 2018 and the symptoms started the next day on 18 Apr 2018. |
| 19-Apr-2018 | UAE; 18US021727; TX; U.S.A | **Species:** Rabbit<br>**Breed:** Albino<br>**Sex:** M<br>**Sex qualifier:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | 17-Apr-2018 | 18-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 19 April 2018, the owner reported the following event for Roger, a 8 pound, Albino rabbit.<br>17 April 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied topically to the skin between the shouder blades on |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Age:** -<br>**Weight:** 8 lbs | | | | 12% SPOT ON<br>**Other products used:** Advantage for Cats;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No<br>(Species not indicated / recommended) | | | | | the rabbit for the first time.<br>18 April 2018: The rabbit was not eating, drinking, urinating, defecating, and not acting himself.<br>The rabbit has not been taken to the vet for his ongoing symptoms.<br>The owner usually applies Advantage to the rabbit with no issues .<br>There are no other treated rabbits in the home. No further information available. |
| 20-Apr-2018 | UAE; 18US021813; AL; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 2.00 Year(s)<br>**Weight:** 9 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 16-Apr-2018 | 18-Apr-2018 | 2 Day(s) | D-C | Suspected Adverse Event: On 20 Apr 2018, the veterinarian reported the following event for Salem, a 9 pound, 2 year old, neutered male Domestic Shorthair.<br>16 Apr 2018: The cat had FRONTLINE PLUS CATS (lot unknown) 1 vial, topically, between shoulder blades, applied in the clinic for routine application.<br>18 Apr 2018: The cat presented to the clinic for not eating. On exam, the cat had a fever of 103.6F. They treated the cat with amoxicillin and dipyrone.<br>20 Apr 2018: The cat presented back to the clinic for still not eating, irritation of tongue and drooling. The cat had a fever of 104. The cat was treated with genesis.<br>There is no known history on this cat prior to 16 Apr 2018. No further information is expected.<br>UPDATE 03 May 2018: FeLV/FIV, toxoplasmosis, and Corona titers were all negative. Calici titer was 1:40, consistent with vaccination. |
| 20-Apr-2018 | UAE; 18US021868; CA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 19-Apr-2018 | 20-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 20 Apr 2018, the owner reported the following event for a feline (all other signalments unknown).<br>19 Apr 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades.<br>20 Apr 2018: The cat experienced a swollen neck. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 20-Apr-2018 | UAE; 18US021896; PA; U.S.A | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 7 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No | 16-Mar-2018 | 13-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 20 Apr 2018 the owner reported the following event for a spayed female, Yorkshire Terrier (all other signalments unknown).<br>16 Mar 2018: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was given to the dog (unknown route and site of application), by the owner. This was the first dose applied.<br>On an unknown date after the application the dog was lethargic, shaking, and hiding for 2 days after the application.<br>16 Apr 2018: The dog received another dose of the product. The dog had the same symptoms.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | (Treatment / vaccination program not respected) | | | | | UPDATE 25 Apr 2018: The owner reported the following for Lizzy, a 3 year old, 7 pound, Yorkshire Terrier.<br>16 Mar 2018: 1 vial of FRONTLINE (P62922AL) was given to the dog topically from the shoulder blades to the tail, by the owner. The product was foreign label product but the country of origin is unknown.<br>17 Mar 2018: The symptoms started. The dog recovered on an unknown date.<br>12 Apr 2018: The second dose of the product was given.<br>13 Apr 2018: The dog had the same symptoms.<br>15 Apr 2018: The dog was seen by a veterinarian and given subcutaneous fluids, Cerenia and Meloxicam.<br>17 Apr 2018: The dog recovered.<br>No further medical information expected. |
| 20-Apr-2018 | UAE; 18US021911; CA; U.S.A | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Mar-2018 | 04-Mar-2018* | 3 Day(s) | D-D | Suspected Adverse Event: On 23 Apr 2018 the owner reported the following event for Mickey, a 6 year old, neutered male, Siamese (all other signalments unknown).<br>1 Mar 2018: 1 vial of FRONTLINE PLUS CATS (lot unknown) was given to the cat, topically between the shoulder blades, by the owner. This was the first dose applied.<br>4 Mar 2018*: The cat lost hair at the application site.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected. |
| 20-Apr-2018 | UAE; 18US021924; OR; U.S.A | **Species:** Feline<br>**Breed:** Domestic Longhair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 11.00 Year(s)<br>**Weight:** 12 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 10-Apr-2018 | 13-Apr-2018* | 3 Day(s) | D-D | Suspected Adverse Event: 19 April 2018, the owner reported the following event for Chucky, an 11 year old, 12 pound, neutered male Domestic Longhair.<br>10 April 2018: One vial of FRONTLINE PLUS CATS (R40801AW) was topically applied to the cat between the shoulder blades.<br>*13 April 2018: The cat developed hair loss at the application site which is still ongoing.<br>The cat was not seen by the vet. No further medical information expected. |
| 23-Apr-2018 | UAE; 18US022208; SC; U.S.A | **Species:** Canine<br>**Breed:** Dachshund<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 2.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** effitix; iverhart;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 22-Apr-2018 | 23-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 23 April 2018, the owner reported the following event for Lily, a 2 year old, spayed female Dachshund.<br>10 April 2018: Lily was given effitix and iverhart.<br>22 April 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P62927AL) was applied to Lily for the first time.<br>23 April 2018: The dog start to vomit.<br>No further medical information available.<br>Update 03 May 2018: After further review the reportability was changed from 15 Day to periodic. |
| 23-Apr-2018 | UAE; 18US022284; | **Species:** Canine<br>**Breed:** Retriever | 1 | 1 | 0 | **Product used:** FIPRONIL | 21-Apr-2017* | 21-Apr-2018 | 3 Hour(s) | D-C | Suspected Adverse Event: On 23 April 2018, the veterinarian reported the following event for Leo, a 4 year old, 63 pound, |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | MD; U.S.A | Labrador<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 63 lbs | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 272MCG/652MG ;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | neutered male, Retriever mix.<br>21 April 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied topically to Leo. Within 3 hours the dog started to have seizure like activity and developed tremors. The tremoring lasted 5 minutes and the dog recovered without vet assistance.<br>The dog also takes HEARTGARD PLUS (272 MCG/227 MG) (lot and expiration unknown) monthly with no issues. No further medical information expected. |
| 23-Apr-2018 | UAE; 18US022357; TN; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 21 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 23-Mar-2018* | 23-Mar-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 23 April 2018, the owner reported the following event for a 21 pound dog of unknown signalment.<br>*23 March 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was topically applied to the dog. Following the treatment the dog started to constantly itch without the presence of fleas.<br>The owner declined the report. No further medical information expected. |
| 23-Apr-2018 | UAE; 18US022430; OH; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Flat-Coat)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** - | 01-Nov-2017* | 01-Nov-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 23 April 2018, the owner reported the following event for a Retriever (Flat-Coat).<br>*1 Nov 2017: One vial of FRONTLINE PLUS DOG 89-132 (P62805AR) was topically applied to the dog. The dog stated to itch at the application site.<br>*4 Nov 2017: The dog recovered from the itching.<br>No further medical information available |
| 23-Apr-2018 | UAE; 18US022433; FL; U.S.A | **Species:** Canine<br>**Breed:** Vizla<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** 2.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 23-Apr-2018 | 23-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 23 Apr 2018 the owner reported the following event for a 2 year old, Vizsla (all other signalments unknown).<br>23 Apr 2018: 1 vial of FRONTLINE (lot unknown, product unsubstantiated) was given to the dog topically (unknown site of application), by the owner. This was the first dose applied. The owner started noticing dandruff at the site of application .<br>The dog was not seen by a veterinarian or given any treatment.<br>The symptoms are ongoing. No further medical information expected. |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 23-Apr-2018 | UAE; 18US022512; MD; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 12.3 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Fel-O-Vax RCP; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 14-Apr-2018* | 17-Apr-2018* | 3 Day(s) | D-D | Suspected Adverse Event: On 23 Apr 2018, the receptionist reported the following event for MJ, a 6 year old (born 7 Jun 2011), 12.3 pound, spayed female, Domestic Shorthair. 12 Apr 2018: The veterinarian administered 1 mL of Fel-O-Vax RCP, 1 mL, SC, in the left hind leg. 14 Apr 2018: The pet owner applied one vial of FRONTLINE PLUS CATS (P40602AW), topically, between the shoulder blades. It's unknown if she's previously received the product. 17 Apr 2018: The exact date of symptom onset is unknown; however, MJ returned to the veterinarian presenting with scabs and alopecia at the application site partly due to excessive grooming of the area. MJ was treated with an injection of dexamethasone. The adverse symptoms are ongoing. No further medical information expected. |
| 23-Apr-2018 | UAE; 18US022553; CT; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 23-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 23 Apr 2018, the owner reported the following event for a canine (all other signalments unknown). Unknown Date: One vial of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown) was applied between the shoulder blades. The dog experienced redness at application site. It is unknown if the pet was presented to the clinic and if any treatment was provided. The status of the pet is unknown. No further medical information is expected. |
| 23-Apr-2018 | UAE; 18US022561; NJ; U.S.A | **Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 43 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 22-Apr-2014* | 22-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 23 April 2018, the owner reported the following event for Ruby, a 4 year old, 43 pound spayed female Golden doodle. 22 April 2018: One half vial of FRONTLINE PLUS DOG 45-88 LBS (M64001AR) was topically applied to the skin between the shoulder blades to Ruby. Within a few hours after the treatment the dog started eat a lot of grass and vomit. The symptoms are still ongoing. The dog has had FL for several years and have the same reaction after each dose, she recovers in 3-4 days without vet assistance. No further medical information expected. |
| 23-Apr-2018 | UAE; 18US022589; FL; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 9 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / | 18-Apr-2018 | 18-Apr-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 25 Apr 2018 the owner reported the following event for a female, Domestic Shorthair (Crossbreed) (all other signalments unknown). 18 Apr 2018: An unknown amount of FRONTLINE PLUS CATS (R40202B) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. 20 Apr 2018: The cat had an eye infection. The cat is itching all over the body. The cat is lethargic and was unresponsive for 12 |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | hours.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. There was another cat treated with the product that had symptoms (see case 18US023051). No further medical information expected.<br>UPDATE 30 Apr 2018: The owner reported the following event for Layla, 5 year old, approximately 9 pound, spayed female.<br>18 Apr 2018: 1 vial of the product was applied topically between the shoulder blades. This was the first dose applied. The symptoms started the same day.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected. |
| 24-Apr-2018 | UAE; 18US022632; WI; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 24-Apr-2017* | 24-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 24 Apr 2018, the owner reported the following event for Buddy, 5 year old, 6 pound, neutered male, Feline (all other signalments unknown).<br>24 Apr 2018: One vial of FRONTLINE PLUS CATS (P40404AW) was applied between the shoulder blades. The cat ingested the product and began to run around. The cat also experienced hypersalivation and foaming at the mouth. The pet was not presented to the clinic and no treatment was provided. After 10 minutes symptoms improved but are still ongoing.<br>No further medical information is expected. |
| 24-Apr-2018 | UAE; 18US022633; NY; U.S.A | **Species:** Feline<br>**Breed:** American Shorthair<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 14.00 Year(s)<br>**Weight:** 11 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 16-Apr-2017 | 20-Apr-2018 | 4 Day(s) | D-D | Suspected Adverse Event: On 24 Apr 2018, the owner reported the following event for Max,14 year old, 11 pound, neutered male, American Shorthair Feline.<br>16 Apr 2018: One vial of FRONTLINE PLUS CATS (R40606A) was applied between the shoulder blades.<br>20 Apr 2018: The cat experienced hair loss at the application site.<br>24 Apr 2018: Symptoms are still ongoing.<br>No further medical information is expected. |
| 24-Apr-2018 | UAE; 18US022667; PA; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 9.0 lbs | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown | 01-Jan-2018* | 01-Jan-2018* | 0 Day(s) | D-A | Suspected Adverse Event: On 24 Apr 2018, the animal owner reported the following event for an unknown canine of unknown signalment weighing 9.0 pounds.<br>Unknown dates: the canine received HEARTGARD PLUS (68 MCG/57 MG) (lot and expiration) one chew administered orally monthly and FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown) one vial applied topically monthly for an unknown length of time. It is unknown if the canine experienced any outward symptoms. It is unknown if any treatments were administered.<br>The canine passed away an unknown time later.<br>The health status of the canine at the time of administration is unknown. No further medical information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | to Company | | | | | |
| 23-Apr-2018 | UAE; 18US022695; NJ; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Golden)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 40 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 22-Apr-2014* | 22-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 23 April 2018, the owner reported the following event for Chloe, a 5 year old, 40 pound spayed female Golden doodle.<br>22 April 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was topically applied to the skin between the shoulder blades to Chloe. Within a few hours after the treatment the dog started to urinate frequently and urinate in the home. The symptoms are still ongoing.<br>The dog has had FL for several years and has the same reaction after each dose, she recovers in 3-4 days without vet assistance.<br>No further medical information expected. |
| 24-Apr-2018 | UAE; 18US022891; CA; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 23-Apr-2017* | 24-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 24 April 2018, the owner reported the following event for a dog of unknown signalment.<br>23 April 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (FL) (lot unknown) was applied to the dog and it is assumed the dog may have gotten the FL in his eye.<br>24 April 2018: The dog's eyes were swollen and red.<br>The owner explained the dog has had FL in the past with no issues.<br>The owner declined the report. No further medical information expected. |
| 24-Apr-2018 | UAE; 18US022900; MN; U.S.A | **Species:** Feline<br>**Breed:** American Shorthair<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 9.4 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** - | 22-Apr-2011* | 23-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 25 Apr 2018 the owner reported the following event for Nikko, an American Shorthair (all other signalments unknown).<br>22 Apr 2018: An unknown amount of FRONTLINE PLUS CATS (H41302AW) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the cat vomited, was lethargic, and anorexic.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected.<br>UPDATE 25 Apr 2018: The owner reported the following for an approximately 7 year old, 9.4 pound, neutered male.<br>2011*: The cat started on 1 vial of the product applied to the cat topically between the shoulder blades. The cat was treated once a month seasonally form Apr-Nov. The cat had symptoms after every dose was applied. The symptoms would start the day after the application and last about 1 week.<br>22 Apr 2018: The cat received another dose of the product. The cat had the same symptoms.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. The cat has had symptoms with the rabies and distemper vaccines where the cat becomes lethargic. No further medical information expected. |
| 24-Apr-2018 | UAE; 18US022929; -; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 24-Apr-2018* | 24-Apr-2018* | 0 Day(s) | D-C | Suspected Adverse Event: On 24 Apr 2018, a pet owner reported the following event by email for a 1 year old male canine of further unknown signalment. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** 1.00 Year(s)<br>**Weight:** Unknown | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** AFOXOLANER 11.3 MG CHEWABLE TABLETS;<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | Unknown date: The dog received FRONTLINE PLUS (lot number unknown) (product unsubstantiated). After an unknown period of time, the dog developed a kidney infection. The dog received unknown veterinary care.<br>The current status of the dog is unknown.<br>It was noted that the dog previously received NEXGARD (lot number and expiration date unknown) (product unsubstantiated).<br>No further medical information expected. |
| 24-Apr-2018 | UAE; 18US022941; CA; U.S.A | **Species:** Canine<br>**Breed:** Dachshund (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 13 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 24-Oct-2017 | 24-Oct-2017 | 0 Day(s) | D-D | Suspected Adverse Event: On 24 Apr 2018, the owner reported the following event for Penny, 3 year old, 13 pound, spayed female, Dachshund canine.<br>24 Oct 2017: One vial of FRONTLINE PLUS DOG 5-22 LBS (M61902AL) was applied between the shoulder blades. After 10 minutes the dog experienced itching, hair loss, and bumps all over the body.<br>Unknown date: The pet was presented to the clinic. The attending veterinarian administered an unknown steroid injection.<br>24 Apr 2018: The symptoms are still ongoing.<br>There is one other dog in the household that received FRONTLINE and experienced symptoms (see case 18US022950). No further medical information is expected. |
| 24-Apr-2018 | UAE; 18US022950; CA; U.S.A | **Species:** Canine<br>**Breed:** Dachshund<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 24-Oct-2017 | 24-Oct-2017 | 0 Day(s) | D-D | Suspected Adverse Event: On 24 Apr 2018, the owner reported the following event for Lola, 4 year old, 10 pound, spayed female, Dachshund canine.<br>24 Oct 2017: One vial of FRONTLINE PLUS DOG 5-22 LBS (M61902AL) was applied between the shoulder blades. After 10 minutes the dog experienced itching all over the body.<br>Unknown date: The pet was not presented to the clinic.<br>24 Apr 2018: The symptoms are still ongoing.<br>There is one other dog in the household that received FRONTLINE and experienced symptoms (see case 18US022941). No further medical information is expected. |
| 25-Apr-2018 | UAE; 18US023015; NJ; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** PO-Oral<br>**Was the product used ok?:** No (Route not indicated / recommended) | 01-Jan-2018* | 01-Jan-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 25 Apr 2017 the owner reported the following event for a canine (all signalments unknown).<br>Unknown date: An unknown amount of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was given to the dog orally, by the owner.<br>It is unknown if this was the first application. An unknown amount of time after the application, the dog vomited.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected. |
| 23-Apr-2018 | UAE; 18US023051; | **Species:** Feline<br>**Breed:** Maine | 1 | 1 | 0 | **Product used:** FIPRONIL | 18-Apr-2018 | 18-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 25 Apr 2018 the owner reported the following event for a male, Maine Coon Cat/Ragdoll mixed breed |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | FL; U.S.A | Coon Cat<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 14 lbs | | | | 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | (all other signalments unknown).<br>18 Apr 2018: An unknown amount of FRONTLINE PLUS CATS (R40202B) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the cat was lethargic. The cat was chewing around the backside. The cat vomited.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. There was another cat treated with the product that had symptoms (see case 18US022589). No further medical information expected.<br>UPDATE 30 Apr 2018: The owner reported the following for Jasper, a 7 year old, 14 pound, neutered male.<br>18 Apr 2018: 1 vial of the product was applied topically between the shoulder blades. This was the first dose applied. The symptoms started the same day.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected. |
| 25-Apr-2018 | UAE; 18US023108; FL; U.S.A | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 11 lbs | 4 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 04-Mar-2018 | 04-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On ( Date), the owner reported the following event for Chloe, 8 year old, 11 pound, spayed female, Chihuahua canine.<br>4 Apr 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades. Immediately after the dog experienced lethargy and shaking. The pet was not presented to the clinic and no treatment was provided.<br>8 Apr 2018: The pet recovered.<br>The dog also received FRONTLINE on 4 Mar 2018 and no symptoms presented. There are 3 other dogs in the household that also receive the product and are asymptomatic. No further medical information is expected. |
| 25-Apr-2018 | UAE; 18US023143; LA; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 9 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 21-Mar-2018 | 21-Mar-2018 | N/A | D-D | Suspected Adverse Event: On 25 Apr 2018, the owner reported the following event for a 9 pound canine (all other signalments unknown).<br>21 Mar 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades.<br>14 Apr 2018: Another vial was applied.<br>Unknown date: The pet experienced increased itching. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>There are 3 other dogs in the household that also received FRONTLINE and experienced symptoms (see case 18US023578, 18US23592, 18US023588). No further medical information is expected. |
| 25-Apr-2018 | UAE; 18US023163; MN; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 9.00 Year(s)<br>**Weight:** 55 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the** | 24-Apr-2009* | 24-Apr-2018 | 30 Minute(s) | D-D | Suspected Adverse Event: On 25 Apr 2018 the receptionist reported the following event for Zoey, a 9 year old, 55 pound, spayed female, Canine (unknown).<br>2009*: The dog started on FRONTLINE PLUS DOG 45-88 LBS given to the dog topically between the shoulder blades, by the owner. The dog was treated monthly on a seasonal basis.<br>24 Apr 2018: The dog was given another dose of FRONTLINE PLUS DOG 45-88 LBS (P60403AR). Approximately 30 minutes after the application, the dog was lethargic and not eating.<br>The dog was seen by the veterinarian but has not been given any treatment. The symptoms are ongoing. No further medical information expected. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **product used ok?:** Yes | | | | | |
| 25-Apr-2018 | UAE; 18US023164; CT; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 4.50 Year(s) **Weight:** 8 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | 21-Apr-2016 | 21-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 25 April 2018, the owner reported the following event for Jasmine, a 4.5 year old, 8 pound, spayed female Chihuahua.<br>21 April 2018: One half vial of FRONTLINE PLUS DOG 5-22 LBS (L62502AL) was topically applied to the skin between the shoulder blades to the dog. Within 5 minutes the dog began to act extremely strange. She began rubbing her back against furniture and she slept in the other dog's cage.<br>22 April 2018: The dog recovered without veterinarian assistance. The dog has been on FL for the past 2 years with no issues. There is one other treated dog in the home who did not have any issues.<br>No further medical information available. |
| 25-Apr-2018 | UAE; 18US023235; NY; U.S.A | **Species:** Feline **Breed:** American Shorthair **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 24-Apr-2018 | 25-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 25 Apr 2018, the owner reported the following event for an American Shorthair feline (all other signalments unknown).<br>24 Apr 2018: One vial of FRONTLINE PLUS CAT (P41102AX) was applied between the shoulder blades.<br>25 Apr 2018: The cat experienced strange behavior, lethargy and anorexia. The pet was presented to the clinic where the cat was diagnosed with an infection from a cat bite. It is unknown if the pet was treated.<br>26 Apr 2018: The status of the pet is unknown.<br>No further medical information is expected. |
| 13-Apr-2018 | UAE; 18US023419; NY; U.S.A | **Species:** Canine **Breed:** Bichon Frise **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 20.0 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Jan-2016* | 01-Jan-2016* | 0 Day(s) | D-C | Suspected Adverse Event: On 13 Apr 2018, a veterinarian reported the following event for an Unknown 20 pound, *5 year old, neutered male Bichon Frise Mix.<br>On an unknown date, the canine received FRONTLINE (unsubstantiated)(lot and expiration unknown) and an unknown amount of time later began twitching, labored breathing and acting out of it. It is unknown if the canine presented to the clinic for treatment and current status is unknown.<br>The veterinarian also reported another case for this canine, 18US020373. No further medical information availablle.<br>Update 30 Apr 2018: The reporter did not indicate the symptoms were ongoing at the time the event in case18US020373 occurred, so an approximate event end date was entered for this case. |
| 26-Apr-2018 | UAE; 18US023462; NY; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 14 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 26-Mar-2013* | 28-Mar-2018* | 2 Day(s) | D-D | Suspected Adverse Event: On 26 Apr 2018 the owner reported the following event for Danny, an 11 year old, 14 pound, neutered male, Domestic Shorthair (Crossbreed).<br>2013*: The cat started on 1 vial of FRONTLINE PLUS CATS given to the cat topically between the shoulder blades, by the owner. The frequency of application is unknown.<br>26 Mar 2018: The cat received another dose of FRONTLINE PLUS CATS (R40202B).<br>28 Mar 2018*: The cat had a dime sized bald spot at the site of the application.<br>The cat was seen by the veterinarian but was not given any treatment. The symptoms are ongoing. No further medical information expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 26-Apr-2018 | UAE; 18US023540; TX; U.S.A | **Species:** Canine **Breed:** Dalmatian **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 60 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 25-Apr-2018 | 26-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 26 Apr 2018, the owner reported the following event for Louie, 1 year old, 60 pound, neutered male, Dalmatian canine.<br>25 Apr 2018: One vial of FRONTLINE PLUS DOG (product unsubstantiated) (Lot unknown) was applied between the shoulder blades.<br>26 Apr 2018: The dog experienced skin irritation at the application site and vomiting. The hair on the pet at the application site also turned yellow. The pet was not presented to the clinic and no treatment was provided. Symptoms are still ongoing.<br>No further medical information is expected. |
| 26-Apr-2018 | UAE; 18US023578; LA; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 22 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 21-Mar-2018 | 21-Mar-2018 | N/A | D-D | Suspected Adverse Event: On 25 Apr 2018, the owner reported the following event for a 22 pound canine (all other signalments unknown).<br>21 Mar 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades.<br>14 Apr 2018: Another vial was applied.<br>Unknown date: The pet experienced increased itching. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>There are 3 other dogs in the household that also received FRONTLINE and experienced symptoms (see case 18US023143, 18US023588, 18US023592). No further medical information is expected. |
| 26-Apr-2018 | UAE; 18US023588; LA; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 49 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 21-Mar-2018 | 21-Mar-2018 | N/A | D-D | Suspected Adverse Event: On 25 Apr 2018, the owner reported the following event for a 49 pound canine (all other signalments unknown).<br>21 Mar 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>14 Apr 2018: Another vial was applied.<br>Unknown date: The pet experienced increased itching. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>There are 3 other dogs in the household that also received FRONTLINE and experienced symptoms (see case 18US023143, 18US023578, 18US023592). No further medical information is expected. |
| 26-Apr-2018 | UAE; 18US023592; LA; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 80 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not | 21-Mar-2018 | 21-Mar-2018* | N/A | D-D | Suspected Adverse Event: On 25 Apr 2018, the owner reported the following event for a 80 pound canine (all other signalments unknown).<br>21 Mar 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>14 Apr 2018: Another vial was applied.<br>Unknown date: The pet experienced increased itching. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>There are 3 other dogs in the household that also received FRONTLINE and experienced symptoms (see case 18US023143, 18US023578, 18US023588). No further medical information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | respected) | | | | | |
| 26-Apr-2018 | UAE; 18US023619; TN; U.S.A | **Species:** Canine **Breed:** Shepherd Dog (Others) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 70 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 24-Jan-2018 | 25-Apr-2018 | 1 Day(s) | D-C | Suspected Adverse Event: On 26 Apr 2018, the owner reported the following event for Miley, 3 year old, 70 pound, spayed female, Shepherd mix canine.<br>24 Apr 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (P61201AR) was applied between the shoulder blades.<br>25 Apr 2018: The dog experienced lethargy, anorexia, fever, and rash at the application site. The pet was presented to the clinic. The attending veterinarian prescribed Tramadol and Carprofen.<br>26 Apr 2018: Symptoms are still ongoing.<br>The pet has received FRONTLINE monthly since 24 Jan 2018 and no symptoms presented. No further medical information is expected. |
| 27-Apr-2018 | UAE; 18US023689; WI; U.S.A | **Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** Unknown | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 24-Jan-2018 | 31-Jan-2018* | N/A | D-C | Suspected Adverse Event: On 27 April 2018, the owner reported the following event for Murphy, a 4 year old, neutered male Domestic Mediumhair.<br>24 Jan 2018: One vial of FRONTLINE PLUS CATS (P40203BW) was topically treated per the label.<br>*31 Jan 2018: The cat started to lose fur all over, the cat developed a fever, not active, and he is losing weight.<br>24 Feb 2018: The cat was re dosed with another vial and his symptoms continued.<br>The cat has not been seen by the vet for his ongoing symptoms. There is one other treated cat in the home who did not have an issue. No further medical information available. |
| 27-Apr-2018 | UAE; 18US023727; ID; U.S.A | **Species:** Canine **Breed:** Mixed Breeds / various **Sex:** F **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 50 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Apr-2016* | 20-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 27 April 2018, the owner reported the following event for Lucy, a 13 year old, 50 pound, spayed female mixed breed dog.<br>20 April 2018: One vial of FRONTLINE PLUS DOG 89-132 LBS (FL) (P61003AL) was applied to the dog. Following the treatment on an unknown date the dog was not able to move well.<br>*30 April 2018: The dog recovered.<br>The dog has had FL in the past with no issues. No further medical information available. |
| 26-Apr-2018 | UAE; 18US023761; OR; U.S.A | **Species:** Canine **Breed:** Poodle (Standard) **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 48 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 12-Apr-2012* | 12-Apr-2015 | 0 Day(s) | D-C | Suspected Adverse Event: On 26 April 2018, the owner reported the following event for Abhaya, a 11 year old, 48 pound, spayed female Poodle (Standard).<br>12 April 2015: One vial of FRONTLINE PLUS DOG 45-88 LBS (FL) (lot and expiration unknown) was topically applied per label to the dog. Following the application the dog's fur would stain yellow and would remain stained for 2-3 weeks.<br>19 April 2015: The dog was diagnosed with a kidney infection and prescribed an unknown antibiotic.<br>*28 April 2015: The dog recovered.<br>The dog was given FL 6-7 months out the year for years and would seemingly have the same issue every few months. No further medical information expected. |
| 26-Apr-2018 | UAE; | **Species:** Feline | 1 | 1 | 0 | **Product used:** | 21-Apr-2018* | 21-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 24 Apr 2018, the following event |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | 18US023840; MT; U.S.A | **Breed:** Domestic Longhair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 12.75 lbs | | | | FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** unknown medications; Onsior;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Route not indicated / recommended) | | | | | was reported to Safety Call International (SCI) by the veterinarian for Prancer, a 10 year old*, 12.75 pound, neutered male Domestic Longhair.<br>Unknown date: He had a dental prophylaxis with an unknown number of dental extractions. He received unknown medications in relation to the procedure. He received Onsior post operatively for an unknown length of time.<br>21 Apr 2018: He received an application of FRONTLINE PLUS FOR CATS (P41003AW) topically on an unknown shoulder by the owner. A small amount splashed on the pet's face. The owner did notice if pet ingested any of the product. An unknown time post application, he began experiencing hypersalivation and decreased appetite.<br>Unknown date: He presented to the veterinary clinic. On physical examination, his dental extraction site was noted had healed well. It is unknown if any diagnostics or treatments were initiated. His current condition is unknown.<br>No further medical information expected. |
| 27-Apr-2018 | UAE; 18US023874; -; U.S.A | **Species:** Canine<br>**Breed:** Terrier Breeds (500 Series)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 24-Mar-2018 | 24-Mar-2018 | N/A | D-D | Suspected Adverse Event: On 27 April 2018, the owner reported the following event for a Terrier (signalment unknown).<br>24 March 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (FL) (R60830AL) was topically applied to the dog. A few days after the treatment the dog developed little red pimples with white heads on the dog's stomach.<br>27 April 2018: Another vial of FL was applied and the owner is seeing the same reaction.<br>The owner declined the report. No further medical information expected. |
| 27-Apr-2018 | UAE; 18US023928; OH; U.S.A | **Species:** Feline<br>**Breed:** Domestic Longhair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 18 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 11-Apr-2018* | 27-Apr-2018 | 16 Day(s) | D-D | Suspected Adverse Event: On 27 Apr 2018, the owner reported the following event for Pus Pus, 3 year old, 18 pound, spayed female, Domestic Longhair feline.<br>11 Apr 2018: One vial of FRONTLINE PLUS CAT (lot unknown) was applied between the shoulder blades.<br>27 Apr 2018: The cat experienced hair loss at the application site. The pet was not presented to the clinic and no treatment was provided. Symptoms are still ongoing.<br>No further medical information is expected. |
| 27-Apr-2018 | UAE; 18US023948; VA; U.S.A | **Species:** Canine<br>**Breed:** Basset Hound<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 2.00 Year(s)<br>**Weight:** 48 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous | 22-Apr-2018 | 25-Apr-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 27 Apr 2018 the owner reported the following event for Daisy, a 2 year old, 48 pound, spayed female, Basset Hound.<br>22 Apr 2018: 1 vial of FRONTLINE PLUS DOG 45-88 LBS (P61908AR) was given to the dog topically from the shoulder blades to the tail, by the owner. This was the first dose applied.<br>25 Apr 2018: The dog had sores all down the back at the application site.<br>The dog was seen by the veterinarian and given Cephalexin, Rimadyl, and Synacore. The symptoms are ongoing. No further medical information expected. |

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| | | | | | | **Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | |
| 30-Apr-2018 | UAE; 18US024185; TX; U.S.A | **Species:** Canine<br>**Breed:** Catahoula<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 9.00 Year(s)<br>**Weight:** 70 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 23-Apr-2016 | 27-Apr-2018 | 4 Day(s) | D-D | Suspected Adverse Event: On 30 Apr 2018, the owner reported the following event for a Osiris, 9 year old, 70 pound, neutered male, Catahoula canine.<br>23 Apr 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201AR) was applied between the shoulder blades.<br>27 Apr 2018: The dog experienced swelling at the application site. The affected area also filled with fluid. The pet was not presented to the clinic and no treatment was provided.<br>1 May 2018: Symptoms are still ongoing.<br>No further medical information is expected. |
| 30-Apr-2018 | UAE; 18US024341; CT; U.S.A | **Species:** Canine<br>**Breed:** Mixed Breeds / various<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 29-Apr-2014* | 29-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 30 Apr 2018, the owner reported the following event for Bo, 4 year old, 10 pound, neutered male, Mixed Breed canine.<br>29 Apr 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60525AL) was applied between the shoulder blades. The pet experienced hyperactivity. The dog was running around acting like the product burned. The pet was not presented to the clinic and no treatment was provided. The pet recovered after 20 minutes.<br>The dog has received FRONTLINE monthly since 29 Apr 2014* and no symptoms presented. No further medical information is expected. |
| 30-Apr-2018 | UAE; 18US024377; NY; U.S.A | **Species:** Canine<br>**Breed:** Tibetan Terrier<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 15.00 Year(s)<br>**Weight:** 24 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Apr-2003* | 01-Oct-2017* | N/A | D-C | Suspected Adverse Event: On 30 Apr 2018 the owner reported the following event for Angie, 15 years, 24 pounds, spayed female, Tibetan Terrier.<br>2003*: The dog started on 1 vial of FRONTLINE PLUS DOG 23-44 LBS given to the dog topically between the shoulder blades, by the owner. The dog is treated seasonally from Feb-Nov.<br>Oct 2017*: The dog started having an uneven gape (spacing between the back legs). The symptoms are more prevalent in the morning and evening. The symptoms are continuous throughout the month and do not seem to change with subsequent doses.<br>1 Apr 2018: The dog received the most recent dose of FRONTLINE PLUS DOG 23-44 LBS (R61020AL). The symptoms are ongoing.<br>The dog was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 30-Apr-2018 | UAE; 18US024384; PA; U.S.A | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** M<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | 01-Jan-2018* | 01-Jan-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 30 Apr 2018, the receptionist reported the following event for Mac, a 10 year old (born 2 Feb 2007) unknown weight male neutered Miniature Poodle.<br>Unknown date: The dog was treated with an application of FRONTLINE (unsubstantiated) (lot unknown). Following on an |

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| | | Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** Unknown | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | unknown date, the dog had redness at the application site and then recovered on an unknown date.<br>Case was reported with case US18024372. No further medical information expected. |
| 01-May-2018 | UAE; 18US024521; NC; U.S.A | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 6.14 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 25-Apr-2018* | 26-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 30 Apr 2018, the following event was reported to Safety Call International (SCI) by the veterinarian for Sprinkles, a 6.14 pound, 7 year old*, spayed female Siamese mix.<br>25 Apr 2018: Sprinkles received FRONTLINE PLUS CATS (P40203BW) topically between the shoulder blades. Sprinkles accidentally ingested product from her paw.<br>26 Apr 2018: Sprinkles was lethargic and was making a possible choking/gagging<br>sound while eating which then progressed to sounding more like respiratory irritation through the weekend.<br>30 Apr 2018: Sprinkles presented to the clinic and X-rays were performed. DVM discovered bronchial irritation and also anisocoria during physical exam.<br>Her current status is unknown at this time. No further information at this time. |
| 01-May-2018 | UAE; 18US024578; NY; U.S.A | **Species:** Canine<br>**Breed:** Terrier (Jack Russell)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 17 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** DELMOPINOL 35 MG ORAL CHEWABLE TABLET; Sentinel;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Sep-2015 | 06-Mar-2018* | N/A | D-D | Suspected Adverse Event: On 1 May 2018, the owner reported the following event for Wesley, 5 year old, 17 pound, neutered male, Jack Russell Terrier canine.<br>6 Mar 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P61522AL) was applied between the shoulder blades. One dose of ORAVET DENTAL HYGIENE CHEW M was administered orally.<br>Unknown date: The dog experienced excessive hair loss. The pet was not presented to the clinic and no treatment was provided.<br>9 Apr 2018: Symptoms still ongoing. Another vial was applied. One dose of ORAVET DENTAL HYGIENE CHEW M was administered orally.<br>1 May 2018: Symptoms are still ongoing.<br>The dog has received FRONTLINE monthly since 1 Sept 2015 and symptoms presented. The dog has also received Sentinel monthly since 1 Sept 2015. No further medical information is expected. |
| 01-May-2018 | UAE; 18US024670; WI; U.S.A | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 1.00 Year(s)<br>**Weight:** 13 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-May-2017 | 27-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 1 May 2018, the owner reported the following event for Patches, 1 year old, 13 pound, spayed female, Shih Tzu mix canine.<br>27 Apr 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades. Immediately after the pet experienced hyperactivity. The dog ran around like the product was irritating the skin. The pet was not presented to the clinic. The owner bathed the pet and the pet recovered.<br>The pet has received FRONTLINE sporadically since 1 May 2017 and the same symptoms presented. There is 1 other dog in the household that also received the FRONTLINE and no symptoms presented. No further medical information is expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 01-May-2018 | UAE; 18US024739; MO; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 20 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 17-Apr-2016* | 17-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 1 May 2018, the owner reported the following event for Frankie, 2 year old, 20 pound, neutered male, Feline (all other signalments unknown). 17 Apr 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. Immediately after the pet experienced intense itching. The pet was not presented to the clinic and no treatment was provided. 1 May 2018: Symptoms are still ongoing. The pet has received the product sporadically since 17 Apr 2016* and no symptoms presented. There are 6 other cats in the household that also received FRONTLINE and experienced symptoms (see case 18US024761, 18US024771, 18US024790, 18US024797, 18US024808, and 18US024812). No further medical information is expected. |
| 01-May-2018 | UAE; 18US024761; MO; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 17 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 17-Apr-2016 | 17-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 1 May 2018, the owner reported the following event for Louie, 2 year old, 17 pound, neutered male, Feline (all other signalments unknown). 17 Apr 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. Immediately after the pet experienced intense itching. The pet was not presented to the clinic and no treatment was provided. 1 May 2018: Symptoms are still ongoing. The pet has received the product sporadically since 17 Apr 2016* and no symptoms presented. There are 6 other cats in the household that also received FRONTLINE and experienced symptoms (see case 18US024739, 18US024771, 18US024790, 18US024797, 18US024808, and 18US024812). No further medical information is expected. |
| 01-May-2018 | UAE; 18US024771; MO; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 24 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 17-Apr-2016 | 17-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 1 May 2018, the owner reported the following event for Rio, 2 year old, 24 pound, spayed female, Feline (all other signalments unknown). 17 Apr 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. Immediately after the pet experienced intense itching. The pet was not presented to the clinic and no treatment was provided. 1 May 2018: Symptoms are still ongoing. The pet has received the product sporadically since 17 Apr 2016* and no symptoms presented. There are 6 other cats in the household that also received FRONTLINE and experienced symptoms (see case 18US024739, 18US024761, 18US024790, 18US024797,18US024808, and 18US024812). No further medical information is expected. |
| 01-May-2018 | UAE; 18US024790; MO; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 20 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 17-Apr-2016* | 17-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 1 May 2018, the owner reported the following event for Lucky, 2 year old, 20 pound, spayed female, Feline (all other signalments unknown). 17 Apr 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. Immediately after the pet experienced intense itching. The pet was not presented to the clinic and no treatment was provided. 1 May 2018: Symptoms are still ongoing. The pet has received the product sporadically since 17 Apr 2016* and no symptoms presented. There are 6 other cats in the household that also received FRONTLINE and experienced symptoms (see case 18US024739, 18US024761, 18US024771, 18US024797,18US024808, and 18US024812). No further medical information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 01-May-2018 | UAE; 18US024797; MO; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 17 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 17-Apr-2016 | 17-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 1 May 2018, the owner reported the following event for Miss Kitty, 5 year old, 17 pound, spayed female, Feline (all other signalments unknown).<br>17 Apr 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. Immediately after the pet experienced intense itching. The pet was not presented to the clinic and no treatment was provided.<br>1 May 2018: Symptoms are still ongoing.<br>The pet has received the product sporadically since 17 Apr 2016* and no symptoms presented. There are 5 other cats in the household that also received FRONTLINE and experienced symptoms (see case 18US024739, 18US024761, 18US024771, 18US024790,18US024808, 18US024812). No further medical information is expected. |
| 01-May-2018 | UAE; 18US024808; MO; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 22 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 17-Apr-2016* | 17-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 1 May 2018, the owner reported the following event for Tuxedo, 2 year old, 22 pound, neutered male, Feline (all other signalments unknown).<br>17 Apr 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. Immediately after the pet experienced intense itching. The pet was not presented to the clinic and no treatment was provided.<br>1 May 2018: Symptoms are still ongoing.<br>The pet has received the product sporadically since 17 Apr 2016* and no symptoms presented. There are 6 other cats in the household that also received FRONTLINE and experienced symptoms (see case 18US024739, 18US024761, 18US024771, 18US024790,18US024797, 18US024812). No further medical information is expected. |
| 01-May-2018 | UAE; 18US024812; MO; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 14 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 17-Apr-2016* | 17-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 1 May 2018, the owner reported the following event for Angel, 2 year old, 14 pound, spayed female, Feline (all other signalments unknown).<br>17 Apr 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. Immediately after the pet experienced intense itching. The pet was not presented to the clinic and no treatment was provided.<br>1 May 2018: Symptoms are still ongoing.<br>The pet has received the product sporadically since 17 Apr 2016* and no symptoms presented. There are 6 other cats in the household that also received FRONTLINE and experienced symptoms (see case 18US024739, 18US024761, 18US024771, 18US024790,18US024797, 18US024808). No further medical information is expected. |
| 01-May-2018 | UAE; 18US024844; PA; U.S.A | **Species:** Canine **Breed:** Soft Coated Wheaton **Sex:** M **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 46.000 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 01-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 1 May 2018, the owner reported the following event for Bing, 7 year old, 46 pound, neutered male, Soft Coated Wheaton canine.<br>1 May 2018: One vial of FRONTLINE PLUS DOG 48-88 LBS (P61401AR) was applied between the shoulder blades. Immediately after the pet experienced itching and redness at the application site. The pet was not presented to the clinic and no treatment was provided. Symptoms are still ongoing.<br>The pet has received the product on prior unknown date and no symptoms presented. No further medical information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 02-May-2018 | UAE; 18US025087; WA; U.S.A | **Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** M **Sex qualifier:** - **Age:** 10.00 Year(s) **Weight:** 60 lbs | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | N/A | 28-Apr-2018 | 1 Day(s) | D-A | Suspected Adverse Event: On 2 May 2018, the owner reported the following event for Bear, an approximately 10 year old, approximately 60 pound, intact male, Retriever ( Labrador, Black). 27 Apr 2018: 1 vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was given to the dog topically between the shoulder blades, by the owner. The dog has been on the product for an unknown amount of time. 28 Apr 2018: The dog started vomiting, was lethargic, and was drinking a lot of water. The dog was not seen by a veterinarian or given any treatment. The dog died on 5 May 2018. No further medical information expected. |
| 02-May-2018 | UAE; 18US025113; NJ; U.S.A | **Species:** Canine **Breed:** Medium crossbred (10 - 20 Kg) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 24 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Phytovet; **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-May-2017* | 01-May-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 2 May 2018, a veterinary clinic staff member reported the following event for Sheba, a 2 year old (born on 7 May 2014), 24 pound, spayed female mixed breed canine. Unknown date: The dog received FRONTLINE PLUS (lot number unknown) (product unsubstantiated). After an unknown period of time, the dog developed a rash. Unknown date: The dog fully recovered. It was noted that Sheba receives Phytovet for allergies. No further medical information expected. |
| 02-May-2018 | UAE; 18US025224; FL; U.S.A | **Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 63 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 02-May-2009* | 02-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 2 May 2018, the owner reported the following event for Chloe, 9 year old, 63 pound, spayed female, Labrador Retriever mix canine. 2 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades. The pet experienced discoloration at the application site. The area turned purple. The pet was not presented the clinic and no treatment was provided. Symptoms are still ongoing. The dog has received FRONTLINE since 2 May 2009* and no symptoms presented. There is 1 other dog in the household that also experienced symptoms after using the product (see case 18US025225). No further medical information is expected. |
| 02-May-2018 | UAE; 18US025225; FL; U.S.A | **Species:** Canine **Breed:** Retriever Labrador **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 70 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical and Opthalmic **Was the product used ok?:** Yes | 02-May-2009* | 02-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 2 May 2018, the owner reported the following event for Ella, 9 year old, 70 pound, spayed female, Labrador Retriever mix canine. 2 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades. The pet experienced discoloration at the application site. The area turned purple. The pet was not presented the clinic and no treatment was provided. Symptoms are still ongoing. The dog has received FRONTLINE since 2 May 2009* and no symptoms presented. There is 1 other dog in the household that also experienced symptoms after using the product (see case 18US025224). No further medical information is expected. |
| 03-May-2018 | UAE; 18US025446; TX; U.S.A | **Species:** Canine **Breed:** Chihuahua | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 03-May-2018 | 03-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 3 May 2018, the owner reported the following event for Holly, 5 month old, 5 pound, intact female, Chihuahua canine. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** F<br>**Sex qualifier:** -<br>**Age:** 5.00 Month(s)<br>**Weight:** 5 lbs | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | 3 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R61421AL) was applied between the shoulder blades. The product ran down the pets legs. The pet experienced itching. The dog has not been presented to the clinic and no treatment was provided. Symptoms are still ongoing.<br>No further medical information is expected. |
| 03-May-2018 | UAE; 18US025474; AZ; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Golden)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 3.50 Year(s)<br>**Weight:** 49.6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 02-May-2018* | 03-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 3 May 2018 the veterinarian reported the following event for Finn, a 3.5 year old, 49.6 pound, neutered male, Golden Retriever- Poodle mix.<br>2 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS. (Lot unknown) was applied between the shoulder blades.<br>3 May 2018: The dog experienced redness at the application site. The pet was treated with Cortisone and presented to the clinic on the same date for an examination.<br>The symptoms are still ongoing to date. There were no other products applied to the pet. No further medical information expected. |
| 03-May-2018 | UAE; 18US025658; -; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-May-2018* | 01-May-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 3 May 2018, the following was reported on a social media website involving a feline with unknown signalment.<br>Unknown date: An application of FRONTLINE (unknown lot number and unknown dosage) was applied to the back of the cat's neck on an unknown date.This was the pet's first exposure to this product. In an unknown amount of time, the cat developed nerve spasms and then developed a burn wound at the site of application. It is unknown if the pet was treated for these symptoms. No other details about this event are known as there are no other updates related to this post. No other medical information is expected. |
| 04-May-2018 | UAE; 18US025662; NC; U.S.A | **Species:** Feline<br>**Breed:** Calico<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 04-May-2018 | 04-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 4 My 2018, the owner reported the following event for a male Calico (signalment unknown).<br>4 May 2018: One vial of FRONTLINE PLUS CATS (R40801AW) was applied to the cat and immediately the cat began to experience agitation and pawing himself 5 minutes later. The cat trying to lick the product off, he was thirsty, and dipping his paws into water.<br>No further medical information available. |
| 04-May-2018 | UAE; 18US025689; CA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | 01-May-2018* | 01-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 4 May 2018, the veterinarian reported the following event via voicemail for a feline of unknown signalment.<br>2018*: Cat was given FRONTLINE (lot number unknown) (product |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | unsubstantiated) and the owner believed it was bleaching the black cat's hair.<br>The veterinarian stated via voicemail that the product was purchased from Amazon and had no codes on the packaging. No further medical information expected. |
| 04-May-2018 | UAE; 18US025774; NJ; U.S.A | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 04-Oct-2017* | 04-May-2018 | 1 Hour(s) | D-D | Suspected Adverse Event: On 4 May 2018, the owner reported the following event for a female Shih Tzu (signalment unknown).<br>4 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R61708BL) was topically applied to the dog. Within one hour the dog started to vomit bile.<br>The dog received a treatment in Oct 2017, and it is unknown if the dog had symptoms. No further medical information available. |
| 04-May-2018 | UAE; 18US025880; NY; U.S.A | **Species:** Canine<br>**Breed:** Poodle (Toy)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2000 | 01-Jan-2000* | 0 Day(s) | D-D | Suspected Adverse Event: On 4 May 2018, the owner reported the following event for a Poodle (Toy) (signalment unknown)<br>*1 Jan 2000: One vial of FRONTLINE PLUS DOG 0-22 LBS (lot unknown) was topically applied to the dog.<br>On an unknown date the dog's fur turned brown at the application site. No further medical information available. |
| 04-May-2018 | UAE; 18US025904; MN; U.S.A | **Species:** Canine<br>**Breed:** Mastiff<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** 3.00 Year(s)<br>**Weight:** 114.5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 03-May-2018 | 04-May-2018 | 1 Day(s) | D-B | Suspected Adverse Event: On 4 May 2018, a veterinarian reported the following event for a 3 year old Mastiff of further unknown signalment.<br>3 May 2018: A pet owner applied FRONTLINE PLUS (lot number unknown) (product unsubstantiated) purchased from Costco.<br>4 May 2018: The dog had hind limb paralysis.<br>No further information at this time.<br>UPDATE 7 May 2018: As reported by the clinic staff, Harli, a 3 year old (born 10 Mar 2015), 114.5 pound, female Mastiff presented to the clinic on 4 May 2018 with hind limb paralysis and was treated with prednisone. A CBC and radiographs performed yielded unremarkable results. The dog's current health status is unknown.<br>No further medical information is expected. |
| 04-May-2018 | UAE; 18US025915; MN; U.S.A | **Species:** Canine<br>**Breed:** Weimaraner<br>**Sex:** U<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | 02-May-2018* | 03-May-2018 | 1 Day(s) | D-C | Suspected Adverse Event: On 4 May 2018, the owner reported the following events for a Weinmaraner (signalment unknown).<br>2 May 2018: One vial of FRONTLINE PLUS DOG (lot unknown) (product unsubstantiated) was applied to the dog.<br>3 May 2018: The dog started to dry heave. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | 4 May 2018: The dog had diarrhea and was off balance. The dog was warm, lethargic, and his snot was cooler than normal.<br>No further medical information expected. |
| 07-May-2018 | UAE; 18US026026; MI; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 07-May-2018 | 07-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 7 May 2018, the owner reported the following event for a dog of unknown signalment.<br>7 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was topically applied to the dog. Following the treatment the dog started vomiting.<br>No further medical information available. |
| 07-May-2018 | UAE; 18US026117; PA; U.S.A | **Species:** Canine<br>**Breed:** Great Dane<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 110 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Low dose) | 07-May-2018 | 07-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 7 May 2018, the owner reported the following event for Emmy, a 5 year old, 110 pound, spayed female, Great Dane.<br>7 May 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was given to the dog topically, between the shoulder blades. This was the first dose applied. The same day, the dog vomited. The dog recovered the same day.<br>The dog was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 07-May-2018 | UAE; 18US026127; TN; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Unknown Rabies Vaccine;<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2018* | 01-Jan-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 7 May 2018, the owner reported the following event for an unknown canine (all signalments unknown).<br>Unknown date: An unknown amount of FRONTLINE PLUS (lot unknown, product unsubstantiated) was given to the dog (unknown route and site of application), by the owner. This was the first dose applied. The dog also had an unknown rabies vaccine the same day. Later in the day, the dog´s mouth was swollen.<br>It is unknown if the dog was seen by a veterinarian. The owner gave the dog Benadryl. The dog's current status is unknown. The dog has had unknown symptoms after a distemper vaccines before. No further medical information expected. |
| 07-May-2018 | UAE; 18US026133; NJ; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON | 05-May-2018 | 05-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 7 May 2018, the owner reported the following event for Gotham, a 1 year old, approximately 10 pound, neutered male, Domestic Shorthair (Crossbreed).<br>5 May 2018: 1 vial of FRONTLINE PLUS CATS (R41206AW) was given to the cat topically between the shoulder blades, by the |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex qualifier:** Neutered<br>**Age:** 1.00 Year(s)<br>**Weight:** 10 lbs | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | owner. This was the first dose applied. The same day, the owner noticed redness and hair loss at the application site. The skin was breaking out and the cat started whining and crying.<br>The cat was seen by a veterinarian and given a bath, Convenia, Dexamethasone, and Prednisolone. The symptoms are ongoing.<br>No further medical information expected. |
| 07-May-2018 | UAE; 18US026212; IA; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Golden)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 9.00 Year(s)<br>**Weight:** 60.6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 272MCG/652MG ;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 29-Sep-2008 | 01-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 7 May 2018, the clinic staff reported the following event for Dakota, a 9 year old (born 22 Jun 2008), 60.6 pound, spayed female Golden Retriever mix.<br>29 Sep 2008: Started on HEARTGARD PLUS (272 MCG/227 MG) (lot and expiration unknown) and FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown) once monthly.<br>1 May 2018*: The pet owner administered 1 chew of HEARTGARD PLUS PO and applied one vial of FRONTLINE PLUS intrascapular. At an unknown time following administration and application, the dog began to tremble.<br>7 May 2018: The dog presented to the clinic with trembling and was prescribed Rimadyl. The veterinarian intends to perform a CBC.<br>The dog has been receiving both products since 29 Sep 2008 with no issues. No further medical information is expected. |
| 07-May-2018 | UAE; 18US026218; OH; U.S.A | **Species:** Canine<br>**Breed:** Australian Shepherd<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Month(s)<br>**Weight:** 35 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Sep-2017* | 07-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 7 May 2018, the owner reported the following event for a female, Australian Shepherd (all other signalments unknown).<br>7 May 2018: An unknown amount of FRONTLINE PLUS DOG 23-44 LBS (R61020AL) was given to the dog (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. The dog became lethargic.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected.<br>UPDATE 17 May 2018: The owner reported the following for Bailey, an 8 month old, 35 pound, spayed female.<br>Sep 2017*: The dog started on 1 vial of the product applied to the dog topically between the shoulder blades.<br>7 May 2018: The dog received another dose. 20 minutes after the application the dog was lethargic.<br>8 May 2018: The dog recovered.<br>The dog was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 07-May-2018 | UAE; 18US026251; -; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 3 | 3 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used** | 01-May-2018* | 01-May-2018* | 0 Day(s) | D-B | Suspected Adverse Event: On 7 May 2018, a pet owner reported the following event for 3 canines of unknown signalment.<br>Unknown dates: The dogs received FRONTLINE (lot number unknown) (product unsubstantiated). After an unknown period of time, the dogs experienced seizures. The dogs did have MRIs performed and received other unknown veterinary care.<br>The current status of the dogs are unknown.<br>No further information at this time. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Unknown to Company | | | | | |
| 07-May-2018 | UAE; 18US026373; CA; U.S.A | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 12.5 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 15-Apr-2017* | 17-Apr-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 7 May 2018, the owner reported the following event for Duke, a 12.5 pound, neutered male Shih Tzu. 15 April 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied to the dog. 17 April 2018: The dog had developed discoloration at the application site and a little beyond. 1 May 2018: The dog recovered without vet assistance. No further medical information available. |
| 08-May-2018 | UAE; 18US026581; PA; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** U **Sex qualifier:** Unknown **Age:** 7.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Jan-2014* | 01-Feb-2014* | N/A | D-B | Suspected Adverse Event: On 8 May 2018, the veterinarian reported the following event for an approximately 7 year old, Chihuahua of further unknown signalment. 2014 (unknown dates): The patient received unknown FRONTLINE (lot unknown) (product unsubstantiated), administered via unknown route, by the pet owner. An unknown duration following, the canine developed severe unknown central nervous system signs which included seizure activity of which the reporter would not further describe. Upon talking with a neurologist, the following differential diagnoses were suspected: granulomatous meningoencephalitis (GME), necrotizing meningoencephalitis (NME), unknown tumor, and/or infarction. After the dog received unknown supportive care, on an unknown date, it recovered. No further medical information expected. UPDATE 8 May 2018: Per the veterinarian, in Feb 2014, the canine developed severe unknown central nervous system signs. The pet was treated with immunosuppressive doses of prednisone. No further medical information expected. |
| 08-May-2018 | UAE; 18US026694; IA; U.S.A | **Species:** Canine **Breed:** Retriever (Labrador, Yellow) **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 92 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Sep-2006* | 17-Sep-2017* | 0 Day(s) | D-C | Suspected Adverse Event: On 8 May 2018, the owner reported the following event for Latte, 12 year old, 92 pound, spayed female, Yellow Labrador Retriever canine. 17 Sept 2017*: One vial of FRONTLINE PLUS DOG 89-132 (G60401AR) was applied between the shoulder blades. After 3 hours the pet experienced labored breathing and panting. The pet was not presented to the clinic and no treatment was provided. 24 Sept 2017: The dog recovered. The dog has received FRONTLINE since 1 Sept 2006 and experienced the same symptoms on 2 other unknown dates. No further medical information is expected. |
| 08-May-2018 | UAE; 18US026732; IL; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** methimazole; | 05-May-2017* | 07-May-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 08 May 2018 the veterinarian made the following report for Sophie, a 6.9 pound, female, spayed 10 year old Domestic Short Hair. 05 May 2018: A dose of FRONTLINE PLUS FOR CATS (Lot H41005BW) was applied topically at the base of the neck. 07 May 2018*: Sophie began scratching at the application site and the skin was irritated. 08 May 2018: Sophie presented for an exam. The area was |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Year(s)<br>**Weight:** 6.9 lbs | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | clipped and cleaned and the cat was treated with Convenia and Dexamethasone SP. The cat is overall in good condition with the excception of being hyperthyroid, for which she is being treated with methimazole.<br>No further medical information is expected. |
| 08-May-2018 | UAE; 18US026780; NH; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** No (Overdose) | 02-May-2018* | 02-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 8 May 2018, the owner reported the following event for two unknown canines (all signalments unknown).<br>2 May 2018: 1 vial of FRONTLINE PLUS DOG 89-132 LBS (lot, expiration) was given to each dog (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the dog's were not eating.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected. |
| 08-May-2018 | UAE; 18US026781; CA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Mediumhair (Crossbred)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 08-May-2018 | 08-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 8 May 2018, the owner reported the following event for a Domestic Medium hair feline (all other signalments unknown).<br>8 May 2018: One vial of FRONTLINE PLUS CATS (L41604BW) was applied between the shoulder blades. The cat ingested the product and experienced foaming at the mouth. It is unknown if the pet was presented to the clinic or if any treatment was provided.<br>The cat recovered.<br>No further medical information is expected. |
| 08-May-2018 | UAE; 18US026798; NY; U.S.A | **Species:** Canine<br>**Breed:** Pit Bull<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 58 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 07-May-2018 | 08-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 8 May 2018, the owner reported the following event for Hope, a 4 year old, 58 pound, spayed female, Pit Bull.<br>7 May 2018: 1 vial of FRONTLINE PLUS DOG 45-88 LBS (R60601BR) was given to the dog topically between the shoulder blades. This was the first dose applied.<br>8 May 2018: The dog was lethargic, had a lack of appetite, and loss of bladder control.<br>The dog was not seen by a veterinarian or given any treatment.<br>The symptoms are ongoing. No further medical information expected. |
| 09-May-2018 | UAE; 18US026810; IN; U.S.A | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 6.00 Year(s)<br>**Weight:** 7 lbs | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other | 05-May-2018 | 05-May-2018 | 6 Hour(s) | D-C | Suspected Adverse Event: On 9 May 2018, the owner reported the following event for Sweetie Pie, 6 year old, 7 pound, intact female, Chihuahua canine.<br>5 May 2018 : One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied between the shoulder blades. After 6 hours the pet experienced twitching in the shoulder region, lethargy, pain at application site, and decreased drinking . The pet |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | was not presented to the clinic. The owner bathed the pet in Dawn five times.<br>9 May 2018: Symptoms are still ongoing.<br>There are 2 other dog in the household that also received FRONTLINE and were asymptomatic. No further medical information is expected. |
| 09-May-2018 | UAE; 18US026963; CA; U.S.A | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 07-May-2018* | 07-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 9 May 2018, the office manager reported the following event for Blue, a spayed female, Siamese mix of further unknown signalment.<br>7 May 2018: The pet owner applied an unknown amount of FRONTLINE SPRAY (R00401A) topically, in unknown locations, on the patient. Immediately following application, the feline experienced acute emesis and diarrhea. The pet owner bathed her in Dawn dish soap and in doing so, the emesis resolved, but the diarrhea is ongoing.<br>No further medical information expected. |
| 09-May-2018 | UAE; 18US027031; CA; U.S.A | **Species:** Canine<br>**Breed:** Boston Terrier<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 18 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 09-May-2018 | 09-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 9 May 2018, the owner reported the following event for Petunia, 3 year old, 18 pound, spayed female, Boston Terrier canine.<br>9 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied between the shoulder blades. The pet experienced a nose bleed. The pet was not presented to the clinic and no treatment was provided. The pet recovered.<br>No further medical information is expected. |
| 09-May-2018 | UAE; 18US027124; MT; U.S.A | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 71.4 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Ear solution; Ketohex wipes;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 06-Apr-2017* | 06-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 9 May 2018, the clinic staff reported the following event for Maggie May, a 10 year old (born 15 Jan 2008), 71.4 pound, spayed female, mixed canine.<br>2017*: Dog was started on seasonal FRONTLINE PLUS DOG 45-88 LBS (P60104AR)<br>6 Apr 2018*: Dog was given first dose of FRONTLINE PLUS for this season. That same day the dog was lethargic and her arthritis flared up.<br>The dog recovered without treatment a couple of days later. The dog was also receiving an unknown ear solution, Ketohex wipes for allergies, and was diagnosed with cancer. There is one other dog in the home that experienced a similar reaction (18US027127). No further medical information expected. |
| 09-May-2018 | UAE; 18US027127; MT; U.S.A | **Species:** Canine<br>**Breed:** Weimaraner<br>**Sex:** F<br>**Sex qualifier:** Neutered | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products** | 06-Apr-2017* | 06-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 9 May 2018, the clinic staff reported the following event for Marnie, an 11 year old (born 10 Jan 2007), 67.6 pound, spayed female, Weimaraner.<br>2017*: Dog was started on seasonal FRONTLINE PLUS DOG 45-88 LBS (P60104AR)<br>6 Apr 2018*: Dog was given first dose of FRONTLINE PLUS for |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Age:** 11.00 Year(s)<br>**Weight:** 67.6 lbs | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | this season. That same day the dog was lethargic.<br>The dog recovered without treatment a couple of days later. There is one other dog in the home that experienced a similar reaction (18US027124). No further medical information expected. |
| 09-May-2018 | UAE; 18US027175; IL; U.S.A | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 06-May-2018* | 06-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 9 May 2018, the owner reported the following event for a Chihuahua canine (all other signalment unknown).<br>6 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (M62201AL) was applied between the shoulder blade. The pet experienced itching. It is unknown if the pet was presented to the clinic or if any treatment was provided.<br>No further medical information is expected. |
| 10-May-2018 | UAE; 18US027257; KY; U.S.A | **Species:** Bovine<br>**Breed:** -<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 16.00 Month(s)<br>**Weight:** 95 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Unknown Heartworm Medication;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Sep-2017* | 08-May-2018 | 4 Day(s) | D-D | Suspected Adverse Event: On 10 May 2018, the owner reported the following event for a male, Bernese Mountain Dog (all other signalments unknown).<br>Unknown Date: An unknown amount of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) was given to the dog topically (unknown site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the dog had skin irritation and hair loss.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected.<br>UPDATE 11 May 2018: The owner reported the following for Bo, an approximately 16 month old, approximately 95 pound, neutered male.<br>Sep 2017*: The dog started on 1 dose of the product given topically between the shoulder blades. The dog also started on an unknown heartworm medication.<br>1 May 2018: The dog was given a dose of the unknown heartworm medication<br>4 May 2018: The dog was given another dose of the FRONTLINE PLUS DOG 89-132 LBS.<br>8 May 2018: The symptoms started.<br>The dog was seen by a veterinarian and given Chlorhexidine and Silver Sulfasalazine. The symptoms are ongoing. No further medical information expected. |
| 10-May-2018 | UAE; 18US027309; OR; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | N/A | 10-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 10 May 2018, the owner reported the following event for a canine (all other signalments unknown).<br>10 May 2018: One vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) was applied between the shoulder blades. The pet experienced skin irritation. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |

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| | | | | | | Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | |
| 10-May-2018 | UAE; 18US027427; FL; U.S.A | **Species:** Canine<br>**Breed:** Hound Breeds (200 Series)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 70 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** IVERMECTIN TABLETS 272 MCG;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Nov-2017 | 06-Apr-2018* | 0 Day(s)* | D-D | Suspected Adverse Event: On 10 May 2018, the owner reported the following event for a Hound (all other signalments unknown).<br>Unknown Date: FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was given to the dog topically (site of application unknown), by the owner. On an unknown date after the application, the dog had hair loss down the back and had slight aggression.<br>UPDATE 17 May 2018: The owner reported the following event for Bruce, 6 year old, 70 pound, neutered male.<br>6 Apr 2018: 1 vial of FRONTLINE PLUS DOG 45-88 was applied between the shoulder blade.<br>15 May 2018: The pet recovered from hair loss.<br>The pet has received the product since 1 Nov 2017 and no symptoms presented. Per the pet owner, the pet also received the HEARTGARD TABLETS (272 MCG) on and unknown date. No further medical information expected.<br>UPDATE 4 Jun 2018: Per distributor representative, the owner reported the HEARTGARD TABLETS also caused confusion and trouble walking in addition to the aggression that was previously reported. No further information is expected. |
| 10-May-2018 | UAE; 18US027545; NH; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** -<br>**Weight:** 20 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 10-May-2018 | 10-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 10 May 2018, the owner reported the following event for Pumpkin, an approximately 20 pound, intact male, Domestic Shorthair (Crossbreed) (all other signalments unknown).<br>10 May 2018: 1 vial of FRONTLINE PLUS CATS (R41212AW) was given to the cat topically between the shoulder blades, by the owner. This was the first dose applied. The cat started drooling and was lethargic.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected. |
| 11-May-2018 | UAE; 18US027649; MO; U.S.A | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 9.00 Year(s)<br>**Weight:** 4.5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG;<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 03-May-2018* | 05-May-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 11 May 2018 a veterinary assistant reported the following event for Bayley, a 9 year old (9 Aug 2008), 4.5 pound, female spayed Yorkshire Terrier cross.<br>3 May 2018: An unknown dose of FRONTLINE (unsubstantiated) (lot unknown) was given to Bayley.<br>4 May 2018: Bayley received 1 chew of HEARTGARD PLUS (68 mcg/57 mg) (lot and expiration unknown).<br>5 May 2018: She presented to the clinic with vomiting and diarrhea and was treated with Cerenia injection, and sent home with FortiFlora, metronidazole, and Cerenia. A fecal was performed that showed bacteria.<br>Bayley's signs were improving, but her current status is unknown. She has received the HEARTGARD PLUS in the past without issues. No further information at this time. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 11-May-2018 | UAE; 18US027663; WI; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 09-May-2018* | 09-May-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 11 May 2018, the owner reported the following event for a dog of unknown signalment.<br>9 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was topically applied to the dog. Following the treatment the dog was seizing, vomiting, not acting right, the dog also had muscle tremors and drinking a lot of water.<br>The dog has numerous health issues. No further information available. |
| 11-May-2018 | UAE; 18US027924; NC; U.S.A | **Species:** Canine **Breed:** Basset Hound **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 47 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 04-May-2008 | 08-May-2018 | 1 Day(s) | D-C | Suspected Adverse Event: On 11 May 2018, the owner reported the following event for Talula, a 12 year old, 47 pound, spayed female Basset Hound.<br>7 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (P61401) was applied per label to the dog.<br>8 May 2018: The dog was staggering and falling, she also had a loss of appetite.<br>9 May 2018: The dog's appetite returned, but her other symptoms are still ongoing.<br>The dog has been on FL for at least 10 years, and she always loses her appetite for 24 hours following the treatment. No further medical information available. |
| 14-May-2018 | UAE; 18US027987; PA; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 13 lbs | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 04-Apr-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 14 May 2018, the owner reported the following event for Walker, 14 year olf, 13 pound, spayed female, Domestic Shorthair Feline.<br>1 Apr 2018: One vial of FRONTLINE PLUS CATS (P40618) was applied between the shoulder blades.<br>4 Apr 2018: The cat experienced hair loss at the application site. The pet was presented to the clinic and no treatment was provided.<br>14 May 2018: The pet recovered.<br>The cat recived the product on prior unknown date and no symptoms presented. There are 2 other cats in the household that also received FRONTLINE and were aysmptomatic. No further medical information is expected. |
| 14-May-2018 | UAE; 18US028019; NH; U.S.A | **Species:** Canine **Breed:** Boxer **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 55.4 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** - | 09-May-2018* | 09-May-2018* | 0 Day(s) | D-C | Suspected Adverse Event: On 14 May 2018, a veterinarian reported the following event for Aella, a 4 year old, 55.4 pound, spayed female, Boxer.<br>9 May 2018*: The owners applied FRONTLINE PLUS DOG 45-88 LBS (lot unknown) and reported that later in the evening the dog was anorexic and became ataxic in the rear. The owner bathed the dog in dawn dish liquid.<br>10 May 2018*: The owner bathed the dog in dawn dish liquid again.<br>14 May 2018: The dog presented to the clinic and the veterinarian reported the dog is still groggy and the physical exam is WNL. No treatment has been given.<br>The pet owner confirmed no other medications were given, the owner did report the dog is sensitive to many things but has no history of vaccine reactions. The dog had a previous reaction, see |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | case 18US028035. No further medical information expected. |
| 14-May-2018 | UAE; 18US028024; FL; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 14-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 14 May 2018, the owner reported the following event for a Feline (all other signalments unknown). Unknown date: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. The cat experienced increased aggression. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown. No further medical information is expected. |
| 14-May-2018 | UAE; 18US028035; NH; U.S.A | **Species:** Canine **Breed:** Boxer **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 55.4 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 09-May-2017* | 09-May-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 14 May 2018, a veterinarian reported the following event for Aella, a 4 year old, 55.4 pound, spayed female, Boxer. 9 May 2017*: The owners applied FRONTLINE PLUS DOG 45-88 LBS (lot unknown) and reported that later in the evening the dog was groggy during the day. 10 May 2017*: The dog recovered. It is unknown if the dog had any other products or medications. The dog had a similar reaction, see case 18US028019. No further medical information expected. |
| 14-May-2018 | UAE; 18US028064; PA; U.S.A | **Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 15 lbs* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 10-May-2011* | 11-May-2018 | 2 Day(s) | D-B | Suspected Adverse Event: On 14 May 2018, the owner reported the following event for a 7 year old, 15 pound, spayed female, Maltese/Yorkshire Terrier mixed breed. 2011*: The dog started on 1 vial of FRONTLINE PLUS DOG 5-22 LBS (L63507AL) given to the dog topically between the shoulder blades, by the owner. The dog was treated monthly on a seasonal basis from May-Sep. 10 May 2018: The dog was given another dose of the product. 11 May 2018: the dog had 2 seizures. The first seizure lasted about 10 minutes and the second one lasted about 5 minutes. 12 May 2018: The dog had another seizure that lasted about 5 minutes. The dog was seen by the veterinarian but was not given any treatment. The owner gave the dog a Dawn bath. The dog has had symptoms before to an unknown vaccine where the dog was lethargic and had difficulty breathing. No further medical information expected. |
| 14-May-2018 | UAE; 18US028175; SC; U.S.A | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 16 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous | 11-May-2018 | 12-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 14 May 2018, the owner reported the following event for Trouble, 9 year old, 16 pound, neutered male, Shih Tzu canine. 11 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830) was applied between the shoulder blades. 12 May 2018: The pet experienced intense itching. The pet was not presented to the clinic and no treatment was provided. 14 May 2018: Symptoms have improved but are still ongoing. No further medical information is expected. |

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| | | | | | | **Was the product used ok?:** Yes | | | | | |
| 14-May-2018 | UAE; 18US028244; CA; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 14-May-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 14 May 2018, the owner reported the following event for Domestic Shorthair Feline (all other signalments unknown).<br>14 May 2018: One vial of FRONTLINE PLUS CATS (R41013AW) was applied between the shoulder blades. The cat accidentally ingested the product. After 2 minutes the cat vomited. The cat also began running around like the product was irritating. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 14-May-2018 | UAE; 18US028292; MA; U.S.A | **Species:** Canine **Breed:** Great Dane **Sex:** F **Sex qualifier:** - **Age:** 2.00 Year(s) **Weight:** 140 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 272MCG/652MG ; IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 136MCG/326MG ; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | 01-Jul-2016* | 01-May-2018 | 2 Week(s) | D-C | Suspected Adverse Event: On 14 May 2018, a pet owner reported the following event for Matilda, a 2 year old, 140 pound, intact female, Great Dane.<br>2016: The dog started using HEARTGARD PLUS (272 MCG/227 MG)(lot and expiration date unknown)(BROWN), HEARTGARD PLUS (136 MCG/114 MG)(lot and expiration date unknown) (GREEN) and FRONTLINE PLUS DOG 89-132 (lot unknown).<br>23 Apr 2018: The owner administered HEARTGARD PLUS BROWN and GREEN.<br>1 May 2018: The dog presented to the veterinary clinic for pre-op blood work for an upcoming OHE and found that the platelets were low. The dog was doing well and was asymptomatic. The clinic did a fecal that was negative but proactively treated with Panacur.<br>7 May 2018: Blood work was done again and the platelets were even lower than previously.<br>9 May 2018: The dog went to an internist where the owner reported the platelets had decreased even further.<br>10 May 2018: A clinical pathologist confirmed the platelets were low.<br>The owner reports that the dog is acting normally at this time, and no other treatments have been given. No further information at this time. |
| 15-May-2018 | UAE; 18US028395; PA; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 4.50 Year(s) **Weight:** 15 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-May-2018 | 03-May-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 15 May 2018, the owner reported the following event for Fred, an approximately 4.5 year old, approximately 15 pound, neutered male, feline (unknown).<br>1 May 2018: 1 vial of FRONTLINE PLUS CATS (R40719W) was given to the cat topically between the shoulder blades. This was the first dose applied.<br>3 May 2018: The cat had a bald spot at the site of the application. In the middle of the bald spot the skin was red about the size of a quarter.<br>The cat was not seen by a veterinarian. The owner applied Neosporin. The symptoms are ongoing. No further medical information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 15-May-2018 | UAE; 18US028505; NJ; U.S.A | **Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 50 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown Heartworm Medication; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Apr-2018 | 27-Apr-2018 | 1 Week(s) | D-D | Suspected Adverse Event: On 15 May 2018, the owner reported the following event for Nala, a 5 year old, approximately 50 pound, spayed female, Retriever (Golden)/Beagle/Spaniel mixed breed.<br>2013*: The dog started on and unknown Heartworm Medication.<br>2 Apr 2018: The dog received another dose of the unknown Heartworm Medication.<br>20 Apr 2018: 1 dose of FRONTLINE PLUS DOG 45-88 LBS (R61513AR) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied.<br>27 Apr 2018: The dog had skin irritation at the application site. The skin was white and patchy.<br>The dog was not seen by a veterinarian or given any treatment.<br>The symptoms are ongoing. No further medical information expected. |
| 15-May-2018 | UAE; 18US028612; NC; U.S.A | **Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 72 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 11-May-2018 | 12-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 15 May 2018, the owner reported the following event for Sadie, 1 year old, 72 pound, spayed female, German Shepherd canine.<br>11 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201AR) was applied between the shoulder blades.<br>12 May 2018: The pet experienced increased itching.<br>15 May 2018: The symptoms are still ongoing.<br>No further medical information is expected. |
| 15-May-2018 | UAE; 18US028632; CA; U.S.A | **Species:** Feline **Breed:** Calico **Sex:** F **Sex qualifier:** Lactating **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 15-May-2018* | 15-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 15 May 2018, the owner reported the following event for a non-pregnant lactating intact female, Calico (all other signalments unknown).<br>15 May 2018: An unknown amount of FRONTLINE PLUS CATS (R40719AW) was given to the cat topically (unknown site of application), by the owner. It is unknown if this was the first application. The cat started hissing, acting afraid, and would not let the owner touch her.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. The cat is currently nursing 2 day old kittens. No further medical information expected. |
| 15-May-2018 | UAE; 18US028647; TX; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 16.00 Year(s) **Weight:** 17 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 24-Apr-2018 | 27-Apr-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 15 May May 2018, the owner reported the following event for Ernie, 16 year old, 17 pound, spayed female, Domestic Shorthair Feline.<br>24 Apr 2018: One vial of FRONTLINE PLUS CAT (P40414AW) was applied between the shoulder blades.<br>27 Apr 2018: The pet experienced hair loss and scabbing at the application site.<br>15 May 2018: The symptoms have improved but are still ongoing.<br>No further medical information is expected. |

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| 15-May-2018 | UAE; 18US028703; HI; U.S.A | **Species:** Canine **Breed:** Shih Tzu **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 13-May-2018 | 15-May-2018 | 2 Day(s) | D-C | Suspected Adverse Event: On 15 May 2018, the owner reported the following event for Tina, 9 year old, 6 pound, spayed female, Shih Tzu canine.<br>13 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades.<br>15 May 2018: The pet experienced a seizure at 7:30 AM lasting a few seconds. The pet was presented to the clinic. A blood chemistry was run. No treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 15-May-2018 | UAE; 18US028748; CA; U.S.A | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 7.8 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 14-May-2018 | 14-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 15 May 2018, the owner reported the following event for a neutered male, Poodle (all other signalments unknown).<br>14 May 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was given to the dog topically (unknown site of application), by the owner. It is unknown if this was the first application.<br>15 May 2018: The dog was lethargic and not eating.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected.<br>UPDATE 11 Jun 2018 NH: The owner reported the following event for Oliver, 12 year old, 7.8 pound canine.<br>14 May 2018: One vial was applied between the shoulder blade for the first time. After 3 hours the pet experienced lethargy, anorexia, and vomiting. The pet was presented to the clinic. The attending veterinarian prescribed an unknown product to prevent dehydration.<br>17 May 2018: The pet recovered.<br>No further medical information expected. |
| 16-May-2018 | UAE; 18US028812; OH; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 9 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 17-May-2016* | 19-May-2016* | 2 Day(s) | D-D | Suspected Adverse Event: On 16 May 2018, the owner reported the following event for Milly, a 4 year old, approximately 9 pound, spayed female, feline (unknown).<br>2016*: 1 vial of FRONTLINE PLUS CATS (lot unknown) was applied to the cat topically between the shoulder blades, by the owner. This was the first dose applied. Approximately 2 days after the application, the owner noticed the fur falling out at the application site. Approximately 3 days later, the cat recovered.<br>The cat was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 16-May-2018 | UAE; 18US028891; CA; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 7.00 Year(s) **Weight:** 13 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL | 01-Jan-2013* | 16-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 17 May 2018, the owner reported the following event for Love, approximately 7 year old, 13 pound, spayed female, canine (unknown).<br>2013*: The dog started on an unknown amount/portion (split vial between 2 dogs) of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) given to the dog topically, between the shoulder blades by the owner. The dog also started on 1 dose of HEARTGARD PLUS (lot unknown, expiration unknown, product unsubstantiated).<br>1 May 2018: The dog was given another dose of HEARTGARD PLUS. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | PAMOATE CHEWABLE 68MCG/163MG; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | 15 may 2018: The dog was given another dose of FRONTLINE PLUS DOG 89-132 LBS.<br>16 May 2018: The dog broke out in blisters around the mouth, nose, and eyes.<br>The dog was not seen by a veterinarian or given any treatment. The owner gave the dog a bath. The symptoms are ongoing. No further medical information expected. |
| 16-May-2018 | UAE; 18US029012; OR; U.S.A | **Species:** Canine **Breed:** Terrier Breeds (500 Series) **Sex:** M **Sex qualifier:** - **Age:** 4.00 Month(s) **Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 15-May-2018 | 15-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 16 May 2018, the owner reported the following event for Bear, 4 month, 10 pound, intact male, Australian Terrier canine.<br>15 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60525AL) was applied between the shoulder blades. The pet experienced diarrhea, disorientation, and vomiting. The pet was not presented to the clinic and no treatment was provided.<br>16 May 2018: The symptoms have improved but are still ongoing. No further medical information is expected. |
| 17-May-2018 | UAE; 18US029113; IN; U.S.A | **Species:** Canine **Breed:** Retriever Labrador **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 90 lbs | 2 | 2 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 30-Apr-2018* | 14-May-2018* | 2 Week(s) | D-D | Suspected Adverse Event: On 17 May 2018, the owner reported the following event for two approximately 90 pound, Retriever Labradors (all other signalments unknown).<br>30 Apr 2018*: An unknown amount of FRONTLINE SPRAY (R00401A) was given to the dog topically all over the body, by the owner. This was the first application.<br>14 May 2018*: The dog started scratching. The owner is not seeing any flea activity.<br>The dogs were not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected. |
| 17-May-2018 | UAE; 18US029126; FL; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 3 | 3 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 25-Feb-2018 | 25-Feb-2018 | N/A | D-D | Suspected Adverse Event: On 17 May 2018, the owner reported the following event for 3 felines (all other signalments unknown).<br>25 Feb 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades.<br>Unknown date: The cats experienced itching. It is unknown if the pet were presented to the clinic or if any treatment was provided. The status of the pets are unknown.<br>The pets also received the product on 25 Mar 2018 and 25 Apr 2018 and symptoms continued. No further medical information is expected. |
| 17-May-2018 | UAE; 18US029134; NC; U.S.A | **Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON | 17-May-2018 | 17-May-2018 | 1 Hour(s) | D-D | Suspected Adverse Event: On 17 May 2018, the owner reported the following event for Ollie, 1 year old, 15 pound, neutered male, Domestic Mediumhair canine.<br>17 May 2018: One vial of FRONTLINE PLUS CATS (R41013AW) was applied between the shoulder blades. About 1 hour later the |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Neutered<br>**Age:** 1.00 Year(s)<br>**Weight:** 15 lbs | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | pet experienced lethargy. The pet was not presented to the clinic and no treatment was provided. The symptoms are still ongoing. No further medical information is expected. |
| 17-May-2018 | UAE; 18US029145; GA; U.S.A | **Species:** Feline<br>**Breed:** Siamese<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 16-Jan-2018* | 16-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 17 May 2018, the owner reported the following event for Simon, 5 year old, 6 pound, neutered male, Siamese feline.<br>16 May 2018: One vial of FRONTLINE PLUS CATS (R41206A) was applied between the shoulder blades. After a few minutes the pet experienced vomiting. The pet was not presented to the clinic and no treatment was provided. Symptoms are still ongoing.<br>The cat also received the product on 16 Jan 2018* and no symptoms presented. No further medical information is expected. |
| 17-May-2018 | UAE; 18US029183; WA; U.S.A | **Species:** Canine<br>**Breed:** Pomeranian<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 12-May-2018* | 13-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 17 May 2018, the owner reported the following event for a Pomeranian mix canine (all other signalments unknown).<br>12 May 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (R61020AL) was applied at a unknown location.<br>13 May 2018: The pet experienced increased itching. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>There is one other dog in the home that received the product and experienced symptoms (see case 18US029805). No further medical information is expected. |
| 17-May-2018 | UAE; 18US029206; IL; U.S.A | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 66 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 272MCG/652MG ;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 07-May-2017* | 16-May-2018 | 9 Day(s) | D-D | Suspected Adverse Event: On 17 May 2018, the CVT reported the following event for Lucy, 66 pound, 5 year old, spayed female Retriever Labrador.<br>7 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied per label to the dog.<br>16 May 2018: The dog developed a chemical burn and hair loss at the application site.<br>17 May 2018: The dog was seen by the vet and given antibiotics and the owners were instructed to give the dog an oatmeal bath. The dog has had FL before for an unknown length of time with no issues. The dog is also treated with HEARTGARD PLUS (272 MCG/227 MG) (lot and expiration unknown) monthly and has been with no issues. No further medical information available. |
| 17-May-2018 | UAE; 18US029338; | **Species:** Canine<br>**Breed:** Canine | 1 | 1 | 0 | **Product used:** FIPRONIL | 15-May-2018* | 17-May-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 17 May 2018, the owner reported the following event for a canine (all other signalments unknown). |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | NH; U.S.A | (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | 15 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (M64310AL) was applied at a unknown location.<br>17 May 2018: The pet experienced anorexia, red skin, bumps, itching, and a swollen chin. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 05-Jun-2018 | UAE; 18US029369; CA; U.S.A | **Species:** Canine<br>**Breed:** Bichon Frise<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 15.00 Year(s)<br>**Weight:** Unknown | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-May-2018 | 15-May-2018* | 2 Week(s) | D-D | Suspected Adverse Event: On 5 Jun 2018 the owner reported the following event for an unknown canine.<br>1 May 2018: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was given to the dog (unknown route and site of application), by the owner. This was the first dose applied. The dog had fleas.<br>15 May 2018*: The dog started chewing and pulling out fur.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected.<br>UPDATE 19 Jul 2018: The owner reported the following for Gi Gi, a 15 year old, spayed female, Bichon Frise (all other signalments unknown).<br>1 May 2018: 1 vial of the product (R60830AL) was given to the dog topically between the shoulder blades.<br>15 May 2018*: The symptoms started. The owner also reported lethargy.<br>24 May 2018*: The dog recovered.<br>The dog was seen by the veterinarian and given AB injection, Amoxicillin, Vetalog injection, and an unknown skin treatment.<br>There was a new puppy brought into the home around that time and did also receive a treatment but did not have any symptoms.<br>No further medical information expected. |
| 17-May-2018 | UAE; 18US029456; MA; U.S.A | **Species:** Canine<br>**Breed:** Australian Shepherd<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 55.1 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** RECOMBITEK LYME - 2126.R0;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 17-May-2018 | 6 Week(s) 4 Day(s) | D-D | Suspected Lack of Efficacy Claim: On 17 May 2018, the veterinarian reported the following event for Sasha, a 10 year old (born 26 Mar 2008*), 55.1 pound, spayed female, Australian Shepherd mix.<br>Unknown dates (either 2009 or 2011): The patient received an unknown course of treatment with minocycline from another clinic. It's not noted in the medical record what the antibiotic therapy was for.<br>Unknown dates: On an unknown date, the pet owner began applying unknown FRONTLINE (lot unknown) (product unsubstantiated), topically, in an unknown location. An unknown dose has since been applied seasonally from 1 Apr (unknown year) until the first hard snow of each year.<br>Sasha tested Lyme antigen positive via 4Dx Plus tests at the previous clinic on an unknown date in 2013 (moderate positive), and 2 Jun 2014 (faint positive), but was not treated.<br>She then tested Lyme antigen negative via 4Dx Plus tests at that same clinic on 29 Jun 2015 and 12 May 2016, and again at the reporting clinic on 25 May 2017.<br>The patient was vaccinated by an unknown clinic staff member at the reporting clinic with RECOMBITEK LYME (42216, 3 Oct 2018), 1 mL, SC, in the left hip on 25 May 2017 and 15 Jun 2017.<br>1 Apr 2018*: Unknown FRONTLINE was applied by the pet owner. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | 17 May 2018: When Sasha presented for her annual vaccination, she tested Lyme antigen positive via routine 4Dx Plus test. No further diagnostics nor treatment has been initiated.<br>Sasha has no prior Lyme vaccination history and the reporter 's level of suspicion that RECOMBITEK LYME failed to protect the dog is unknown. No further medical information expected.<br>UPDATE 18 June 2018 Quantitative C6 was 106 on 18 May 2018.Urinalysis was unremarkable. The patient was treated with doxycycline. |
| 17-May-2018 | UAE; 18US029473; WI; U.S.A | **Species:** Canine<br>**Breed:** Rat Terrier<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 20 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 15-May-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 17 May 2018, the owner reported the following event for Lola, 4 year old, 20 pound, spayed female, Rat Terrier canine.<br>13 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades.<br>15 May 2018: The pet experienced intense itching. The pet was not presented to the clinic and no treatment was provided.<br>17 May 2018: Symptoms are still ongoing.<br>The pet has received the product on prior unknown date and no symptoms presented. No further medical information is expected. |
| 18-May-2018 | UAE; 18US029493; NY; U.S.A | **Species:** Canine<br>**Breed:** Shar Pei<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 7.00 Year(s)<br>**Weight:** 49 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 17-May-2018 | 18-May-2018 | 1 Day(s) | D-C | Suspected Adverse Event: On 18 May 2018, the owner reported the following event for Nayeli, a 7 year old, 49 pound, non-pregnant non-lactating intact female, Shar Pei.<br>17 May 2018: 1 vial of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was given to the dog topically on the back near the tail, by the owner. This was the first dose applied.<br>18 May 2018: The dog's face was swollen and the dog was itching. The dog was not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected. |
| 18-May-2018 | UAE; 18US029508; NY; U.S.A | **Species:** Canine<br>**Breed:** Medium crossbred (10 - 20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 19.00 Month(s)<br>**Weight:** 24 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Low dose) | 01-Jan-2018* | 15-May-2018 | 4 Day(s) | D-D | Suspected Adverse Event: On the 18 May 2018, a veterinarian reported the following event for Lima, a 24 pound, 19 month old (born 18 Oct 2016), spayed female, Small Crossbred.<br>11 May 2018: The dog received 1 vial of FRONTLINE PLUS 5-22 LBS (lot number unknown) between the shoulder blades by the pet owner.<br>15 May 2018: The dog experienced hyperactivity at night, she was pacing and biting her back all night long.<br>16 May 2018: The dog presented to the clinic with ongoing symptoms, during the examination the veterinarian realized that the patient was very sensitive to the touch in the lower back. The veterinarian treated with Rimadyl and ACEPROMAZINE 10 mg. The symptoms are ongoing. The dog has been on monthly FRONTLINE PLUS since approximately 1 Jan 2018, without any issues. No further information available at this time. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 18-May-2018 | UAE; 18US029650; TX; U.S.A | **Species:** Feline **Breed:** Siamese **Sex:** M **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 13 lbs | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 27-Apr-2007* | 11-May-2018* | 2 Week(s) | D-C | Suspected Adverse Event: On 18 May 2018, the owner reported the following event for Bud, an approximately 11 year old, 13 pound, neutered male, Siamese.<br>2007*: The cat started on 1 vial of FRONTLINE PLUS CATS (R40601) was given to the cat topically between the shoulder blades, by the owner.<br>27 Apr 2018*: The owner applied another dose of the product.<br>11 May 2018*: The owner started noticing fleas on the cat. The cat started not being able to stand up and losing a lot of weight. The vet said the cat was anemic and the RBC level was 9.<br>The cat was seen by a veterinarian but was not given any treatment. The symptoms are ongoing. No further medical information expected. |
| 18-May-2018 | UAE; 18US029656; MI; U.S.A | **Species:** Canine **Breed:** Shih Tzu **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 25 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Dec-2017* | 01-Dec-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 18 May 2018, the owner reported the following event for Teddi, a 5 year old, 25 pound, neutered male Shih Tzu.<br>*1 Dec 2017: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was applied to the dog per label. Immediately the dog started squealing, running around, and rolling.<br>3 Dec 2017: The dog recovered without vet assistance.<br>No further medical information available. |
| 18-May-2018 | UAE; 18US029738; FL; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 18-May-2018 | 18-May-2018* | 0 Day(s) | D-C | Suspected Adverse Event: On 18 May 2018, the owner reported the following event for a cat of unknown signalment.<br>*18 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied to the cat. Following the treatment the cat had a seizure.<br>The owner declined the report, no further information available. |
| 18-May-2018 | UAE; 18US029790; MO; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 13.00 Year(s) **Weight:** 17 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 11-May-2018 | 12-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 18 May 2018, the owner reported the following event for Buddy, 13 year old, 17 pound, neutered male, Domestic Shorthair feline.<br>11 May 2018: One vial of FRONTLINE PLUS CATS (R40801AW) was applied between the shoulder blades.<br>12 May 2018: The pet experienced open sores, and hair loss at the application site<br>17 May 2018: The pet was presented to the clinic and no treatment was provided.<br>18 May 2018: Symptoms are still ongoing.<br>There is one other cat in the household that also received FRONTLINE and experienced symptoms (see case 18US029797).<br>No further medical information is expected. |
| 18-May-2018 | UAE; 18US029797; | **Species:** Feline | 1 | 1 | 0 | **Product used:** FIPRONIL | 11-May-2018 | 12-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 18 May 2018, the owner reported the following event for Buster, 13 year old, 15 pound, neutered |

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| | MO; U.S.A | **Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 13.00 Year(s)<br>**Weight:** 15 lbs | | | | 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | male, Domestic Shorthair feline.<br>11 May 2018: One vial of FRONTLINE PLUS CATS (R40801AW) was applied between the shoulder blades.<br>12 May 2018: The pet experienced irritation, and hair loss at the application site<br>17 May 2018: The pet was presented to the clinic and no treatment was provided.<br>18 May 2018: Symptoms are still ongoing.<br>There is one other cat in the household that also received FRONTLINE and experienced symptoms (see case 18US029790). No further medical information is expected. |
| 18-May-2018 | UAE; 18US029805; WA; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 12-May-2018* | 13-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 17 May 2018, the owner reported the following event for a canine (all other signalments unknown).<br>12 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades.<br>13 May 2018: The pet experienced increased itching. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>There is one other dog in the home that received the product and experienced symptoms (see case 18US029183). No further medical information is expected. |
| 21-May-2018 | UAE; 18US029848; NY; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Labrador, Yellow)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 21-May-2018 | 21-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 21 May 2018, the owner reported the following event for a male Yellow Lab (signalment unknown).<br>*21 May 2018: One vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) was applied to the dog.<br>On an unknown date the dog started losing fur at the application site. The owner declined the report. No further medical information expected. |
| 21-May-2018 | UAE; 18US029995; NY; U.S.A | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 6.00 Year(s)<br>**Weight:** 6.2 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** RECOMBITEK C4 - 13D1.R1; ORAL BORDETELLA CANINE - 1081.01 - PHN3259;<br>**Route:** unknown<br>**Was the** | 01-May-2018* | 14-May-2018 | 13 Day(s) | D-D | Suspected Adverse Event: On 21 May 2018, the office manager reported the following event for Chase, a 6 year old (born 22 Dec 2011), 6.2 pound, intact male, Yorkshire Terrier.<br>13 May 2018: The patient was vaccinated by the veterinarian with RECOMBITEK C4 (45548B10529, 19 Mar 2019), 1 mL, SC, in the right elbow, and RECOMBITEK ORAL BORDETELLA (33014BUNKNOWN, 6 Aug 2019), 1 mL, PO.<br>14 May 2018: Chase became painful where RECOMBITEK C4 was given. The clinician prophylactically dispensed buprenorphine to treat the symptom.<br>16 May 2018: The canine recovered.<br>It's unknown if Chase has previously received RECOMBITEK C4; however, this was his first time receiving RECOMBITEK ORAL BORDETELLA. It was not realized at the time of vaccination that the canine previously experienced a similar event to an unknown distemper vaccine in 2016. No further medical information expected. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **product used ok?:** Unknown to Company | | | | | UPDATE 21 May 2018: Per the records received:<br>5 Feb 2016: Chase received RECOMBITEK C4 (45471AUNKNOWN, 21 Nov 2016), 1 mL, SC, in an unknown location, for the first time, and IMRAB 3 TF, and experienced adverse symptoms. (See case 18US030706).<br>Unknown date: He received unknown FRONTLINE (lot unknown) (product unsubstantiated), administered by the pet owner.<br>13 May 2018: RECOMBITEK C4 was actually given in the right hind leg, not the right elbow as originally reported. It was also noted at the time of vaccination, the patient had been wheezing upon excitement since an unknown date prior and presented with Grade 2 dental disease.<br>No further medical information expected. |
| 21-May-2018 | UAE; 18US030122; FL; U.S.A | **Species:** Canine<br>**Breed:** Terrier Breeds (500 Series)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 13.00 Year(s)<br>**Weight:** 28 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 136MCG/326MG ; Cyclosporine drops; Cyclosporine Tablets;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Aug-2017* | 17-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 21 May 2018, the owner reported the following event for an unknown Terrier (all other signalments unknown).<br>16 May 2018: An unknown amount of FRONTLINE PLUS DOG 23-44 LBS (P61007AL) was given to the dog (unknown route and site of application), by the owner. It is unknown if this was the first dose applied.<br>17 May 2018: The dog was lethargic and laying around. The dog also had a lack of appetite.<br>20 May 2018: The dog recovered.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. No further medical information expected.<br>UPDATE 22 May 2018: The owner reported the following for Jack, a 13 year old, approximately 28 pound, neutered male.<br>2013*: The dog started on 1 dose of HEARTGARD PLUS (136 MCG/114 MG) (7BC0194, 28 Feb 2020) given orally, by the owner. The dog was treated year round. The dog also started on Cyclosporine drops given daily and Cyclosporine Tablets given every 4 days to treat dry eye and dermatitis.<br>Aug 2017*: The dog started on 1 vial of the FRONTLINE PLUS DOG 23-44 LBS (P61007AL) given to the dog topically between the shoulder blades, by the owner. The owner applied for 3 consecutive months but did not apply over the winter.<br>1 May 2018: the dog received another dose of HEARTGARD PLUS (136 MCG/114 MG).<br>16 May 2018 The dog received another dose of FRONTLINE PLUS DOG 23-44 LBS and Cyclosporine Tablets.<br>17 May 2018: The dog received another dose of Cyclosporine drops. The symptoms started.<br>The dog was not seen by a veterinarian or given any treatment. The symptoms are still ongoing. No further medical information expected. |
| 21-May-2018 | UAE; 18US030172; MN; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used** | 17-May-2018* | 18-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 21 May 2018, the owner reported the following event for a neutered male, Domestic Shorthair (Crossbreed) (all other signalments unknown).<br>17 May 2018: An unknown amount of FRONTLINE PLUS CATS (R40801AW) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied.<br>18 May 2018: The cat had skin irritation and hair loss.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Unknown to Company | | | | | |
| 21-May-2018 | UAE; 18US030174; FL; U.S.A | **Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** M **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 16 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 17-May-2017* | 18-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 21 May 2018, the owner reported the following event for Daxter, 12 year old, 16 pound, neutered male, Domestic Mediumhair feline.<br>17 May 2018: One vial of FRONTLINE PLUS CATS (D42103AX) was applied between the shoulder blades.<br>18 May 2018: The pet experienced hair loss at the applicaiton site. The owner bathe the pet with mild soap. The pet was not presented to the clinic.<br>21 May 2018: The symptoms are still ongoing.<br>The pet has recieved the product sporadically since 17 May 2017 and no symptoms presented. No further medical information is expected. |
| 21-May-2018 | UAE; 18US030233; LA; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-May-2018 | 02-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 21 May 2018, the owner reported the following event for a Domestic Shorthair (Crossbreed) (all other signalments unknown).<br>1 May 2018: An unknown amount of FRONTLINE PLUS CATS (R41105W) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied.<br>2 May 2018: The cat vomited once.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected.<br>UPDATE 25 May 2018: The owner reported the following for Chubs, an approximately 2 year old, approximately 6 pound, spayed female, Domestics Shorthair (Crossbreed).<br>1 May 2018: 1 vial of the product was applied topically between the shoulder blades. This was the first dose applied.<br>2 May 2018: the cat only vomited once and recovered.<br>The cat was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 21-May-2018 | UAE; 18US030264; CA; U.S.A | **Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 70 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 11-May-2018 | 11-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 21 May 2018, the owner reported the following event for a Retriever Labrador/Poodle (Standard) (all other signalments unknown).<br>11 May 2018: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (P60902AR) was given to the dog (unknown route and site of application), by the owner. It is unknown if this was the first application. On an unknown date after the application, the dog began to itch worse.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. There was another dog that had symptoms (see case 18US030527). No further medical information expected.<br>UPDATE 31 May 2018: The owner reported the following for Rex, an approximately 5 year old, 70 pound, neutered male, Retriever (Golden)/Poodle (Standard) mixed breed.<br>11 May 2018: 1 vial of the product was applied to the dog topically between the shoulder blades, by the owner. This was the first dose applied. The dog was itching prior to the application but the owner did not see any fleas or ticks. The dog's itching increased after the application.<br>The dog was seen by a veterinarian but was not given any treatment. The symptoms are ongoing. The dog has a prior history |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | of chronic ear infection, incontinence, and a cough. No further medical information expected. |
| 22-May-2018 | UAE; 18US030291; FL; U.S.A | **Species:** Canine **Breed:** Beagle **Sex:** F **Sex qualifier:** Neutered **Age:** 1.50 Year(s) **Weight:** 27 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 136MCG/326MG ; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 18-May-2018 | 18-May-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 22 May 2018, a clinic staff reported the following event for Lam, a 1.5 year old, 27 pound, spayed female, Beagle Mixed Breed. 18 May 2018: The pet was administered HEARTGARD PLUS (136 MCG/114 MG) (lot number and expiration date unknown) and applied FRONTLINE PLUS DOG 23-44 LBS (lot number unknown). The pet was lethargic that night. 19 May 2018: The pet experienced diarrhea. No treatment has been administered. No further medical information expected. |
| 22-May-2018 | UAE; 18US030434; OR; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 11 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 28-Feb-2018* | 29-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 22 May 2018, the owner reported the following event for an 11 pound cat of unknown signalment. 29 April 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied per label. On an unknown date, the cat started clawing behind the ears and back. The cat is also pulling out his fur. The cat does have FAD. There is one other treated cat in the home who also had the same issue, see case 18US030858. No further information available. Update 01 Jun 2018: Upon further review, the reason for assessment was updated. |
| 22-May-2018 | UAE; 18US030499; PA; U.S.A | **Species:** Canine **Breed:** German Shepherd Dog **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 80 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 11-May-2016* | 11-May-2018 | 0 Day(s) | D-B | Suspected Adverse Event: On 22 May 2018, the owner reported the following event for Luda, 4 year old, 80 pound, spayed female, German Shepherd canine. 11 May 2018: One vial of FRONTLINE PLUS DOG (Lot unknown) was applied between the shoulder blades at 1:30 PM. At about 5:30 PM the dog experienced a seizure that lasted 10 seconds. The pet loss vision in the right eye as well. 12 May 2018: The pet was presented to the clinic. The attending veterinarian precribed Prednisone. 22 May 2018: The vision loss is still ongoing. The dog has received the FRONTLINE since 11 May 2016* and not symptoms presented. No further medical information is expected. |
| 21-May-2018 | UAE; 18US030527; CA; U.S.A | **Species:** Canine **Breed:** Wolfhound (Irish) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 90 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Jennison's fido estrogen; | 11-May-2016* | 11-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 22 May 2018, the owner reported the following event for a Wolfhound (Irish) (all other signalments unknown). 11 May 2018: An unknown amount of FRONTLINE PLUS DOG 89-132 LBS (P61705AR) was given to the dog (unknown route and site of application), by the owner. It is unknown if this was the first application. On an unknown date after the application, the dog began to itch worse. It is unknown if the dog was seen by a veterinarian or given any |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | treatment. The dog's current status is unknown. There was another dog that had symptoms (see case 18US030264). No further medical information expected.<br>UPDATE 31 May 2018: The owner reported the following for Poppy, an approximately 8 year old, 90 pound, spayed female.<br>2016*: The dog started on 1 vial of the FRONTLINE PLUS DOG 89-132 LBS was applied to the dog topically between the shoulder blades, by the owner. The dog was not treated regularly and was only treated seasonally.<br>Mar 2018*: The dog started on Jennison's fido estrogen.<br>11 May 2018: The dog received another dose of the FRONTLINE PLUS DOG 89-132 LBS. This was the first dose of the year. The dog was also given a dose of Jennison's fido estrogen. The dog was itching prior to the application but the owner did not see any fleas or ticks. The dog's itching increased after the application. The dog was seen by a veterinarian but was not given any treatment. The symptoms are ongoing. No further medical information expected. |
| 22-May-2018 | UAE; 18US030660; MN; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 13.00 Year(s)<br>**Weight:** 12 lbs | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 22-May-2017 | 21-May-2018 | 0 Day(s) | D-A | Suspected Adverse Event: On 22 May 2018, the veterinarian reported the following event for Cinder, 13 year old, 12 pound, spayed female, Domestic Shorthair feline.<br>21 May 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. After 2 hours the cat passed away.<br>No further medical information is expected.<br>UPDATE 23 May 2018: The veterinarian called to make the following update to the case:<br>The cat ingested the FRONTLINE PLUS after he groomed himself, he was able to reach the product where it was applied. When the owner came across the diceased cat there was some drooling in his mouth. No further information available at this time.<br>UPDATE 21 Jun 2018: Per medical record, a necropsy was performed on 23 May 2018 with the following conclusion: The specific cause of the sudden, unexpected death in this cat was not apparent after gross and histologic examination. The most significant necropsy finding in this cat involved increased left ventricular moderator bands with mild myocardial hypertrophy.This is suggective of cardimyopathy; however, there was no obvious evidence of heart failure making the clinical significance unknown. Renal changes are suggestive of chronic kidney disease and due to the mild nature of the lesions are likely unrelated to the cause of death. The clinical significance of the reported use of FRONTLINE in the time period prior to death is unknown. No further information is expected. |
| 22-May-2018 | UAE; 18US030677; OH; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 01-May-2018* | 01-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 22 May 2018, the owner called to report the following event for a dog of unknown signalment.<br>*1 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied to the dog.<br>The dog had fleas and was constantly scratching at night and the dog was taken to the vet. No further information available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Unknown to Company | | | | | |
| 22-May-2018 | UAE; 18US030687; OH; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 05-May-2018 | 05-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 22 May 2018, the owner reported the following event for a dog of unknown signalment.<br>5 May 2018: One vial of the FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied to the dog.<br>On an unknown date the dog got fleas and was chewing like crazy.<br>The dog is treated with FL monthly. No further information available. |
| 22-May-2018 | UAE; 18US030702; NC; U.S.A | **Species:** Canine **Breed:** Collie **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 20-May-2018* | 21-May-2018 | 1 Day(s) | D-C | Suspected Adverse Event: On 22 May 2018, the owner reported the following event for a Collie canine (all other signalments unknown).<br>20 May 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (M63401BI) was applied at an unknown location.<br>21 May 2018: That morning, the dog experienced vomiting. There was also blood noted in the vomit. It is unknown if the pet was presented to the clinic or if any treatment was provided.<br>There are 3 other dogs in the household that also received the product. One of the dogs also experienced symptoms (see case 18US031252). No further medical information is expected. |
| 23-May-2018 | UAE; 18US030718; ME; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 3 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 22-May-2018* | 23-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 23 May 2018, the owner reported the following event for Lynx, a 2 year old, 3 pound, spayed female Domestic Shorthair.<br>22 May 2018: The cat received one vial of FRONTLINE PLUS CATS (R40601AW) per label.<br>23 May 2018: The cat vomited twice.<br>The cat has not been seen by the vet, no further medical information expected. |
| 23-May-2018 | UAE; 18US030788; -; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | 12-May-2018 | 23-May-2018 | 12 Day(s) | D-D | Suspected Adverse Event: On 23 May 2018, the owner reported the following event for 2 Felines (all other signalments unknown).<br>12 May 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades.<br>23 May 2018: The cats experienced itching. It is unknown if the pets were presented to the clinic or if any treatment was provided.<br>The status of the pets is unknown.<br>No further medical information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **ok?:** Yes | | | | | |
| 23-May-2018 | UAE; 18US030803; OK; U.S.A | **Species:** Canine **Breed:** Pit Bull **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 90 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 12-May-2017* | 23-May-2018* | 11 Day(s) | D-D | Suspected Adverse Event: On 23 May 2018, the owner reported the following event for a 90 pound, male Pit Bull, additional details unknown. 12 May 2017*: Dog began receiving treatment with FRONTLINE PLUS. 12 May 2018: One vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) (FL) was applied between the shoulder blades. 23 May 2018: The owner noticed scabs on the dog's ears. The owner stated that he has seen some flies on the pet in the areas the scabs have presented. The symptoms are ongoing at this time. No further medical information expected. |
| 23-May-2018 | UAE; 18US030811; KY; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 10 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 22-May-2018 | 22-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 23 May 2018, the owner reported the following event for Monkey, 3 year old, 10 pound, spayed female, Feline (all other signalments unknown to owner). 22 May 2018: One vial of FRONTLINE PLUS CATS (Lot unknown) was applied between the shoulder blades. The cat ingested the product. The pet experienced lethargy. The pet was not presented to the clinic and no treatment was provided. 23 May 2018: The symptoms are still ongoing. There is one other cat in the household that also received FRONTLINE and was asymptomatic. No further medical information is expected. |
| 23-May-2018 | UAE; 18US030836; CA; U.S.A | **Species:** Canine **Breed:** Retriever (Labrador, Chocolate) **Sex:** F **Sex qualifier:** Neutered **Age:** 14.00 Year(s) **Weight:** 60 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Proin; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-May-2004 | 21-May-2018 | 1 Day(s) | D-B | Suspected Adverse Event: On 23 May 2018, the owner reported the following event for Jinbiba, a 14 year old, 60 pound, spayed female Chocolate lab. 20 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (FL) (T60604AR) was applied to the dog per the label. 21 May 2018: The dog developed diarrhea, vomiting, seizures, loss of coordination, and collapse. The dog has been on FL all her life and only started having issues that past few months. The dog takes Proin for urinary incontinence and has been for years with no issues. The dog also has arthritis but is in fair health. The dog has not been seen by the vet. No further information available. |
| 22-May-2018 | UAE; 18US030858; OR; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 13 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 28-Feb-2018* | 29-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 22 May 2018, the owner reported the following event for a 13 pound cat of unknown signalment. 29 April 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied per label. On an unknown date, the started clawing behind the ears and back. The cat is also pulling out his fur. The cat does have FAD. There is one other treated cat in the home who also had the same issue, see case 18US030434. No further information available. |
| 23-May-2018 | UAE; 18US030885; | **Species:** Canine **Breed:** Chihuahua | 1 | 1 | 0 | **Product used:** FIPRONIL | 23-Dec-2015* | 23-Dec-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 23 May 2018, the owner reported the following event for Baby, an approximately 18 year old, |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | CA; U.S.A | **Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 18.00 Year(s)<br>**Weight:** 18 lbs | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Lasix; Enacard; Vetmedin pimobendan chewable 2.5 mg NP;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | approximately 18 pound, spayed female, Chihuahua.<br>2015*: The dog started on 1 vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) given to the dog topically between the shoulder blades, by the owner.<br>2016*: The dog started on Lasix and Enacard to treat an unknown heart condition.<br>23 Dec 2017*: The dog was given a dose of all 3 products and also VETMEDIN® (pimobendan) 2.5 mg Chewable Tablet. Within hours of the application, the dog was swaying back and forth and acting drunk. The dog's peripheral vision seemed to be off.<br>24 Dec 2017*: The dog recovered.<br>The dog was not seen by a veterinarian or given any treatment. There were 2 other dogs treated with just the FRONTLINE product and did not have any symptoms. No further medical information expected.<br>UPDATE 25 MAY 2018: Per pet owner, the dog receives VETMEDIN (Product Unsubstantiated) 1/4 tablet in the morning and 1/8 tablet in the evening. The dog has been on VETMEDIN for about 8-10 months. No further information is expected. |
| 22-May-2018 | UAE; 18US030900; OH; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 05-May-2018 | 05-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 22 May 2018, the owner reported the following event for a dog of unknown signalment.<br>5 May 2018: One vial of the FRONTLINE PLUS DOG 23-44 lbs (lot unknown) was applied to the dog.<br>On an unknown date the dog got fleas and was chewing like crazy. The dog is treated with FL monthly. No further information available. |
| 23-May-2018 | UAE; 18US030967; PA; U.S.A | **Species:** Canine<br>**Breed:** Beagle<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 13.00 Year(s)<br>**Weight:** 29 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Pepcid AC;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 22-May-2018 | 22-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 23 May 2018, the owner reported the following event for Bella, a 13 year old, 29 pound, spayed female, Beagle.<br>May 2016*: The dog started on Pepcid AC once a day.<br>22 May 2018: 1 vial of FRONTLINE PLUS DOG 23-44 LBS (R61915AL) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied. The dog also received Pepcid AC. The dog had diarrhea and vomiting.<br>23 May 2018: The dog recovered.<br>The dog was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 23-May-2018 | UAE; 18US030972; WV; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 13.00 Month(s) | 4 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | 23-May-2018 | 23-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 23 May 2018, the owner reported the following event for Cupcake, an approximately 13 month old, 2.5 pound, spayed female, Domestic Shorthair (Crossbreed).<br>23 May 2018: 1 vial of FRONTLINE PLUS CATS (P41102AX) was given to the topically between the shoulder blades, by the owner. This was the first application. The cat licked the product and was vomiting.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing but the cat is doing better. No further medical information expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Weight:** 2.5 lbs | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | |
| 23-May-2018 | UAE; 18US031070; NC; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 9.6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 19-May-2018 | 19-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 23 May 2018, the owner reported the following event for Callie, 10 year old, 9.6 pound, spayed female, Domestic Shorthair feline.<br>19 May 2018: One vial of FRONTLINE PLUS CATS (P40414AW) was applied between the shoulder blades. Immediately after the pet experiencing hypersalivation and vomiting.<br>23 May 2018: The pet was presented to the clinic and no treatment was provided. Symptoms are still ongoing.<br>No further medical information is expected. |
| 23-May-2018 | UAE; 18US031080; NJ; U.S.A | **Species:** Canine<br>**Breed:** Siberian Husky<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 60 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Feb-1999* | 01-Feb-1999* | 0 Day(s) | D-D | Suspected Adverse Event: On 23 May 2018, the owner reported the following event for Jesse, 5 year old, 60 pound, neutered male, Siberian Husky canine.<br>1 Feb 1999: One vial of FRONTLINE TOP SPOT DOGS 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>Unknown date: The pet experienced shaking and panting. The pet was not presented to the clinic and no treatment was provided.<br>The pet recovered.<br>No further medical information is expected. |
| 24-May-2018 | UAE; 18US031108; IA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 8 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 18-May-2016* | 23-May-2018 | 5 Day(s) | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for Grayson, an approximately 10 year old, approximately 8 pound, spayed female, feline (unknown).<br>2016*: The cat started on 1 vial of FRONTLINE PLUS CATS (M40801AW) given to the cat topically between the shoulder blades, by the owner. The cat was only treated as needed.<br>18 May 2018: the cat was given another dose of the product.<br>23 May 2018: The cat was losing hair at the application site.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected. |
| 24-May-2018 | UAE; 18US031120; NE; U.S.A | **Species:** Canine<br>**Breed:** Spaniel<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 17.00 Month(s)<br>**Weight:** 42.4 lbs* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2018* | 22-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 24 May 2018, an office manager reported the following event for Diesel, a 1.5 year old (born 28 Dec 2016), 22 pound, male neutered, Spaniel.<br>Unknown Date: The dog has been using FRONTLINE PLUS DOG 23-44 LBS (lot unknown) for an unknown time without any incident.<br>19 May 2018: The owner applied FRONTLINE PLUS DOG 23-44 LBS.<br>22 May 2018: The owner noticed a burn-like area between the shoulder blades down to the skin and hair loss.<br>23 May 2018: The dog presented to the clinic, reported a hot spot with hair loss down to the skin with blisters and pus. The dog was treated with a clip and clean between the shoulder blades, gentamycin topical spray and cephalexin. No further information at this time. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | UPDATE 24 May 2018: Per the veterinary records, the owner was given a free single dose of FRONTLINE GOLD DOG 23-44 LBS on 30 Mar 2017. The dog's last weight was on 6 Sep 2017 and was 42.4 pounds. No further information at this time.<br>UPDATE 29 May 2018: Per the office manager, FRONTLINE PLUS was actually applied on 21 May 2018. No further medical information expected. |
| 24-May-2018 | UAE; 18US031195; MO; U.S.A | **Species:** Canine<br>**Breed:** Australian Shepherd<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 4.00 Year(s)<br>**Weight:** 47 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Low dose) | 23-May-2018 | 24-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for Blue, 4 year old, 47 pound, intact male, Australian Shepherd canine.<br>23 May 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was applied between the shoulder blades.<br>24 May 2018: The pet experienced weakness which caused inability to walk. The pet was not presented to the clinic and no treatment was provided. Symptoms are still ongoing.<br>No further medical information is expected. |
| 24-May-2018 | UAE; 18US031222; FL; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 24-May-2018* | 24-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for a canine (all other signalments unknown).<br>Unknown date: One vial of FRONTLINE PLUS (product unsubstaniated) (lot unknown) was applied at a unknown location.<br>The pet experienced vomiting and anorexia. The status of the pet is unknown.<br>No further medical information is expected. |
| 24-May-2018 | UAE; 18US031252; NC; U.S.A | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 20-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for a American Dingo canine (all other signalments unknown).<br>20 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (P62005AR) was applied at a unknown location.<br>21 May 2018: That evening the pet experienced vomiting. There was also blood noted in the vomit. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>There are 3 other dogs in the household that also received the product. One of the dogs also experienced symptoms (see case 18US030702).No further medical information is expected. |
| 24-May-2018 | UAE; 18US031346; CA; U.S.A | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Neutered | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other | 05-May-2018* | 12-May-2018* | 1 Week(s) | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for an unknown canine (all signalments unknown).<br>Unknown Date: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (R61108RR) was given to the dog (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the dog |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Age:** 8.00 Year(s)<br>**Weight:** 70 lbs* | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | had hair loss at the application site.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected.<br><br>UPDATE 5 Jun 2018: The owner's daughter reported the following for Condi, an approximately 8 year old, approximately 70 pound, spayed female, Large Crossbreed (>20 kg).<br>5 May 2018*: 1 dose of the product was applied topically between the shoulder blades. This was the first dose applied.<br>12 May 2018*: the symptoms started.<br>The dog was not seen by a veterinarian or given any treatment.<br>The symptoms are ongoing. No further medical information expected. |
| 24-May-2018 | UAE; 18US031371; MD; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 6 | 6 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 18-Apr-2017 | 22-May-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for 6 Domestic Shorthairs (Crossbreed) (all other signalments unknown).<br>18 Apr 2017: The cats started on 1 vial of FRONTLINE PLUS CATS (lot unknown) given to the topically between the shoulder blades, by the owner.<br>19 May 2018: The owner applied another dose of the product. She was not seeing fleas before she applied the product but the cats were scratching.<br>22 May 2018: The owner saw fleas on the cats and the scratching increased.<br>The cats were not seen by a veterinarian or given any treatment.<br>The symptoms are ongoing. No further medical information expected. |
| 24-May-2018 | UAE; 18US031395; TX; U.S.A | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 8 lbs | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Keppra;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-May-2018 | 23-May-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for Lacey Ray, an 8 year old, 8 pound, spayed female, Chihuahua.<br>20 May 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60509AL) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied. The dog also received Keppra to treat a prior history of seizures.<br>23 May 2018: The owner could feel 3 small bumps near the middle of the dogs back on either side of the spine.<br>The dog was seen by a veterinarian and given Benadryl, hexachlor K shampoo, and a dexamethasone injection. The symptoms are ongoing. There were 2 other dogs that had symptoms (see cases 18US31398 and 18US31401). No further medical information expected. |
| 24-May-2018 | UAE; 18US031398; TX; U.S.A | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 10.6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-May-2018 | 21-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for Lydia, a 6 year old, 10.6 pound, spayed female, Chihuahua.<br>20 May 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60509AL) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied.<br>21 May 2018: The owner could feel small bumps all over the dog's body.<br>The dog was seen by a veterinarian and given Benadryl, hexachlor K shampoo, and a dexamethasone injection. The symptoms are ongoing. The dog has vomited before after using First Shield Trio . There were 2 other dogs that had symptoms (see cases 18US31395 and 18US31401). No further medical information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 24-May-2018 | UAE; 18US031401; TX; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 10.2 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-May-2018 | 21-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for Havana, a 6 year old, 10.2 pound, neutered male, Chihuahua.<br>20 May 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60509AL) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied.<br>21 May 2018: The owner could feel about 5 small bumps near the middle of the dogs back and one on the throat.<br>The dog was seen by a veterinarian and given Benadryl, hexachlor K shampoo, and a dexamethasone injection. The symptoms are ongoing. The dog has had lethargy before using First Shield Trio . There were 2 other dogs that had symptoms (see cases 18US31395 and 18US31398). No further medical information expected. |
| 24-May-2018 | UAE; 18US031450; GA; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** - **Age:** 6.00 Year(s) **Weight:** 15 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | 03-May-2018 | 18-May-2018* | 15 Day(s)* | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for Berkley, a 6 year old, approximately 15 pound, intact male, Chihuahua.<br>3 May 2018: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (P62407) was given to the dog topically, between the shoulder blades, by the owner. The owner split the vial between this dog and another dog. This was the first dose applied.<br>18 May 2018*: The dog had diarrhea and vomiting.<br>The dog was not seen by a veterinarian. The owner gave the dog Pedialyte and Pepto Bismol. The symptoms are ongoing. There was another dog that had symptoms (see case 18US031753). No further medical information expected. |
| 24-May-2018 | UAE; 18US031462; TX; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 24-May-2018 | 24-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for an unknown feline (all signalments unknown).<br>24 May 2018: 1 vial of FRONTLINE PLUS CATS (lot unknown) was given to the cat topically (unknown site of application), by the owner. This was the first dose applied. The cat licked the product and started drooling.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected. |
| 21-May-2018 | UAE; 18US031480; NM; U.S.A | **Species:** Canine **Breed:** Newfoundland **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 130 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 17-May-2018* | 21-May-2018* | 4 Day(s) | D-D | Suspected Adverse Event: On the 21 May 2018, the following event was reported to Safety Call International (SCI) by the veterinary technician for Beacon a 130 pound, 4 year old (unknown date of birth), spayed female, Newfoundland.<br>17 May 2018: The owner applied FRONTLINE PLUS 89-132 LBS (P6230AR) between the shoulder blades before boarding the dog for the weekend.<br>21 May 2018: When the owner picked up her dog from boarding she noticed that her dog was experiencing Pruritus on the application site of the FRONTLINE PLUS, often and very vigourously. The dog presented to the clinic where they clipped the area and noticed Dermal irritation/Pain, Dermatological-Edema/Swelling, Dermatological |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | Erythema/Flushed and Dermatological-Laceration/Abrasion.<br>It is unknown when the symptoms started or if the patient has received this product before. No further information available. |
| 25-May-2018 | UAE;<br>18US031487;<br>NC; U.S.A | **Species:** Canine<br>**Breed:** Boxer<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 25-May-2018* | 25-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 25 May 2018, the owner's roommate reported the following event for a Boxer/ Pit Bull mix.<br>*25 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied to the dog.<br>On an unknown date the reported observed the dog acting more aggressively towards the other dog in the home. No further information available. |
| 25-May-2018 | UAE;<br>18US031515;<br>FL; U.S.A | **Species:** Canine<br>**Breed:** Boxer<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 17-May-2017* | 17-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 25 May 2018, the owner reported the following event for Duke, a male Boxer/ Pit mix breed dog.<br>17 May 2018: One vial of FRONTLINE PLUS DOG 89-132 (M63905AR) was applied to the dog.<br>On an unknown date the dog developed mosquito looking bumps on his back and sides. The owner declined the report. There is one other treated dog in the home who also had a reaction. See case 18US032145. No further medical information expected. |
| 25-May-2018 | UAE;<br>18US031571;<br>-; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2018* | 01-Jan-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 25 May 2018 reported the following event for an unknown feline (all signalments unknown).<br>Unknown Date: An unknown amount of FRONTLINE (lot unknown, product unsubstantiated) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date, the cat licked the product and was drooling.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected. |
| 25-May-2018 | UAE;<br>18US031661;<br>WA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the** | 09-May-2018* | 21-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 25 May 2018, the owner reported the following event for a cat (signalment unknown).<br>9 May 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was topically applied to the cat per label.<br>On an unknown date the cat started scratching her neck and running a lot for the last 4 days. The owner declined the report, no further information expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **product used ok?:** Unknown to Company | | | | | |
| 25-May-2018 | UAE; 18US031704; NY; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 01-Jul-2017 | 01-Aug-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 25 May 2018, the owner reported the following event for a Chihuahua/ Jack Russell mix (signalment unknown).<br>*1 Aug 2017: One vial of FRONTLINE PLUS DOG 5-22 LBS (P60507AL) was applied. Within one hour the dog had a lot of nasal discharge, sneezing, and restlessness.<br>The dog had FL the month prior with no issues. The owner declined the report, no further information available. |
| 25-May-2018 | UAE; 18US031713; NC; U.S.A | **Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** - **Age:** 2.00 Month(s) **Weight:** 2 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 25-Apr-2018 | 25-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 25 May 2018, the owner reported the following event for Honey, a 2 month old, 2 pound, intact, female Maltese/ Yorkie mix.<br>25 May 2018: Two sprays of FRONTLINE SPRAY (R00401A) were applied to the dog per label for the first time. Following the treatment the dog was lethargic, drooling, she had muscle spasms, crying, and not eating or drinking. The owner gave the dog Pedialyte, a bath, and a sedative.<br>27 May 2018: The dog recovered without vet assistance.<br>There is one other treated dog in the home who did not have any issues. No further medical information expected.<br><br>Product quality: As reported by the pet owner, a 250 mL bottle of FRONTLINE SPRAY (R00401A) smelled of rubbing alcohol. The product was kept in the off position when it was not being used. Product return not expected, the product cannot be returned. No further information available. |
| 24-May-2018 | UAE; 18US031753; GA; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 8 lbs* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | 03-May-2018 | 06-May-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 24 May 2018, the owner reported the following event for Mel-B, a 6 year old, approximately 8 pound, spayed female, Chihuahua.<br>3 May 2018: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (P62407) was given to the dog topically, between the shoulder blades, by the owner. The owner split the vial between this dog and another dog. This was the first dose applied.<br>6 May 2018: The dog had diarrhea.<br>The dog was not seen by a veterinarian. The owner gave the dog Pedialyte and Pepto Bismol. The symptoms are ongoing. There was another dog that had symptoms (see case 18US031450). No further medical information expected. |
| 25-May-2018 | UAE; 18US031786; GA; U.S.A | **Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other | 25-May-2018 | 25-May-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 25 May 2018, the owner reported the following event for Hannah, 6 year old, 37 pound, spayed female, Jack Russell Terrier canine.<br>25 May 2018: One vial of FRONTLINE PLUS DOG 23-44 (R60516BL) was applied between the shoulder blades. After 3 hours the pet experienced bumps all over the body. The pet was not presented to the clinic and no treatment was provided. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 37 lbs | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | Symptoms are still ongoing.<br>No further medical information is expected. |
| 29-May-2018 | UAE; 18US031807; VA; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 29-May-2018* | 29-May-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 29 May 2018, the owner reported the following event for a dog of unknown signalment.<br>29 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied to the dog. Following the treatment the dog was shivering, shaking, docile doesn't want to move, and is under clear duress.<br>The owner declined the report. No further medical information available. |
| 29-May-2018 | UAE; 18US031854; NC; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 73 lbs | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 06-May-2018 | 06-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 29 May 2018, the owner reported the following event for 2 dogs, approximately 73 pound of unknown signalment.<br>6 May 2018: Both dogs were given one vial of FRONTLINE PLUS 45-88 LBS (lot unknown) each.<br>The owner is seeing 50 fleas on the dog and noticed itching and scratching only after the treatment. The owner declined the report.<br>No further information available. |
| 29-May-2018 | UAE; 18US031883; IL; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-May-2010* | 01-May-2010* | 0 Day(s) | D-C | Suspected Adverse Event: On 29 May 2018, the owner reported the following event for a dog of unknown signalment.<br>*1 May 2010: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied to the dog. Following the treatment the dog would stagger for a day.<br>The owner declined the report. No further information available. |
| 29-May-2018 | UAE; 18US031976; OH; U.S.A | **Species:** Canine<br>**Breed:** Beagle<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 15.00 Year(s)<br>**Weight:** 28 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** | 28-May-2017* | 28-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for a 28 pound, 15 year old, Beagle.<br>*28 May 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (M62606AL) (FL) was topically applied to the dog's back. Following the treatment the dog did not want to eat, dog was sick, and had vomiting and diarrhea all night. The owner gave the dog a bath.<br>29 May 2018: The dog symptoms started to improve, but she has |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | Cyclosporine; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | | | | | not been seen by the vet.<br>The dog has had FL for years with no issues. The dog takes Cyclosporine for fistula<br>No further medical information available. |
| 30-May-2018 | UAE; 18US032003; TX; U.S.A | **Species:** Canine **Breed:** Dachshund (Miniature) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 11 lbs | 6 | 6 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 22-May-2018* | 22-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for 6 approximately 10-12 pound Dachshunds (miniature).<br>22 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P62015) was topically applied to the dogs.<br>The dogs already exhibited itchy behavior prior to the treatment, but after the treatment the itchiness increased. No further medical information available. |
| 29-May-2018 | UAE; 18US032011; AL; U.S.A | **Species:** Canine **Breed:** Belgian Malinois **Sex:** F **Sex qualifier:** - **Age:** 7.00 Month(s) **Weight:** 63 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 21-May-2018 | 26-May-2018 | 5 Day(s) | D-C | Suspected Adverse Event: On 29 May 2018, the owner reported the following event for Lima, a 7 month old, 63 pound, intact female Belgian Malinois.<br>21 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was topically applied per label to the dog for the first time.<br>26 May 2018: A red sore with oozing was noticed on the dog at the application site.<br>28 May 2018: The dog had a fever and was taken to the emergency vet. At the clinic the dog had a fever of 105.3 and her white blood cell count was elevated. She was given two antibiotics and a prescription of oral steroids. A CBC was done and she was send home the same day.<br>The redness of the sore is gone and the fever is gone, but the sore is still present and oozing yellow pus. No further medical information available. |
| 29-May-2018 | UAE; 18US032053; TX; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** 1.00 Year(s) **Weight:** 5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 27-May-2018* | 27-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 27 May 2018, the following event was reported to Safety Call International (SCI) by the pet owner for Little Girl, a 1 year old 5 pound intact female Domestic Shorthair.<br>27 May 2018: The pet owner applied a full tube of FRONTLINE PLUS CATS (R41206AW) topically to the cat and the cat licked it. The cat was gagging after ingestion. The pet owner gave some cat food and the pet recovered.<br>It is unknown if the cat has received the product prior. No further medical information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 29-May-2018 | UAE; 18US032059; GA; U.S.A | **Species:** Canine **Breed:** Border Terrier **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 15 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 24-May-2018* | 25-May-2018* | 1 Day(s) | D-D | Suspected Adverse Event: On 29 May 2018, the veterinarian reported the following event for Moxie, a 15 pound, 4 year old (born 13 Oct 2013), spayed female Border Terrier.<br>24 May 2018: Moxie started on the FRONTLINE PLUS 5-22 LBS (Lot Unknown).<br>25 May 2018*: The owner noticed the pet was extremely lethargic and sore in it's back legs. They also noticed that the pet was walking in a hunched matter.<br>28 May 2018: The vet called to get update on pet. The owner stated that pet is improving, but the symptoms are ongoing.<br>29 May 2018: The pet presented and the vet stated that the pet seemed fine and was considered to be recovered. No further medical information expected. |
| 29-May-2018 | UAE; 18US032142; MI; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Unknown **Age:** 15.00 Year(s) **Weight:** 15 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 25-May-2012* | 25-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 29 May 2018, the owner reported the following event for Lily, a 15 year old, 15 pound, female, Domestic Shorthair.<br>25 May 2018: One vial of FRONTLINE PLUS CATS (P40305AW) (FL) was applied between the shoulder blades. Following the application, the pet was lethargic. The cat has displayed with lethargy with previous applications.<br>26 May 2018: Lethargy subsided in 24 hours of application. Pet owner later found that the pet's fur was missing and the skin was burned and irritated at the site of application.<br>The site was treated with ice compresses and cortisone cream.<br>The site of irritation is no longer spreading and starting to heal but the fur is still missing.<br>No further medical information expected. |
| 25-May-2018 | UAE; 18US032145; FL; U.S.A | **Species:** Canine **Breed:** Boxer **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 17-May-2017* | 17-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 25 May 2018, the owner reported the following event for Duchess, a female Boxer/ Pit mix breed dog.<br>17 May 2018: One vial of FRONTLINE PLUS DOG 89-132 (M63905AR) was applied to the dog.<br>On an unknown date the dog developed mosquito looking bumps on his back and sides. The owner declined the report. There is one other treated dog in the home who also had a reaction. See case 18US031515. No further medical information expected. |
| 29-May-2018 | UAE; 18US032161; AZ; U.S.A | **Species:** Canine **Breed:** Australian Sheep Dog **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Month(s) **Weight:** 52 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 26-Apr-2018 | 29-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 29 May 2018, the owner reported the following event for a 52 pound, Australian Sheep Dog (all other signalments unknown).<br>Unknown Date: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was given to the dog topically (unknown site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date, the dog started rubbing up against everything the rub the product off.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected.<br>UPDATE 8 Jun 2018: The owner reported the following for Izzy, a 9 month old, spayed female, Australian Sheep Dog/Poodle (standard) mixed breed. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | 26 Apr 2018: The dog started on 1 vial of the product given topically between the shoulder blades.<br>29 May 2018: The dog was given another dose of the product. Approximately 30 minutes later the symptoms started. The dog also vomited.<br>30 May 2018: the dog recovered.<br>The dog was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 30-May-2018 | UAE; 18US032258; OR; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 7 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 18-May-2018* | 18-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for a 7 pound, feline (all other signalments unknown).<br>18 May 2018: An unknown amount of FRONTLINE PLUS CATS (lot unknown) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the cat vomited. It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. There were 2 other cats that had symptoms (see case 18US032737 and 18US032738). No further medical information expected.<br>UPDATE 18 Jul 2018: The owner reported this cat did not have any symptoms. |
| 30-May-2018 | UAE; 18US032311; KS; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 56.4 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 12-May-2018* | 29-May-2018 | 17 Day(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for a 56.4 pound, canine (all other signalments unknown).<br>12 May 2018: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was given to the dog (unknown route and site of application), by the owner. It is unknown if this was the first dose applied.<br>29 May 2018: The owner started seeing fleas and the dog started scratching.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected. |
| 30-May-2018 | UAE; 18US032344; CA; U.S.A | **Species:** Canine<br>**Breed:** Maltese<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 8.00 Month(s)<br>**Weight:** 8 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 28-May-2018 | 29-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for Zorro, an 8 month old, 8 pound, intact male, Maltese/Poodle mixed breed.<br>28 May 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied.<br>29 May 2018: Approximately 4-5 hours after the application, the dog started vomiting.<br>The dog was seen by a veterinarian and given an unknown anti-nausea medication, unknown antibiotics, hydrated and a bath. The symptoms are ongoing. No further medical information expected. |
| 30-May-2018 | UAE; 18US032534; GA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products | 01-Jan-2018* | 01-Jan-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 31 May 2018, the owner reported the following event for a Domestic Shorthair (Crossbreed) (all other signalments unknown).<br>Unknown Date: An unknown amount of FRONTLINE PLUS CATS (R40601AW) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, that cat started drooling and froze with its tail up. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Weight:** Unknown | | | | **Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected. |
| 30-May-2018 | UAE; 18US032546; TX; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 100 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 07-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for Sadie, a 100 pound, canine (all other signalments unknown).<br>7 May 2018*: An unknown amount of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) was given to the dog (unknown route and site of application), by the owner. The owner treats on a year round basis but it is unknown how long. On an unknown date after the application, the owner saw fleas on the dog and the dog was chewing on itself and bleeding.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. The re was another dog treated with the product that had symptoms (see case 187US032934). No further medical information expected. |
| 30-May-2018 | UAE; 18US032551; MD; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2018* | 01-Jan-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for an unknown feline (all signalments unknown).<br>Unknown Date: An unknown amount of FRONTLINE (lot unknown) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date the cat's skin was pink at the application site<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected. |
| 31-May-2018 | UAE; 18US032581; IN; U.S.A | **Species:** Canine<br>**Breed:** Feist<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 4.00 Year(s)<br>**Weight:** 18 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 28-Apr-2018 | 28-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for Rosco, a 4 year old, 18 pound, intact male Feist.<br>28 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied to Rosco per label for the second time.<br>The dog had fleas and was itching before the treatment and itching increased after the treatment.<br>The owner applied Hydrocortisone to offer relief, the dog has not been seen. No further information available. |
| 31-May-2018 | UAE; 18US032656; MD; U.S.A | **Species:** Canine<br>**Breed:** Tulear Cotton<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the** | 30-Apr-2018* | 31-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 31 May 2018, the owner reported the following event for a Tulear Cotton (signalment unknown).<br>*31 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P60507AL) was topically applied to the dog.<br>On an unknown date the dog experienced redness and hair loss at the application site after the application and a previous application given in April 2018. No further medical information available. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | **product used ok?:** Unknown to Company | | | | | |
| 30-May-2018 | UAE; 18US032737; OR; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 8.000 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 18-May-2018* | 25-May-2018* | 1 Week(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for an 8 pound, feline (all other signalments unknown).<br>18 May 2018: An unknown amount of FRONTLINE PLUS CATS (lot unknown) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the cat vomited. It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. There were 2 other cats that had symptoms (see case 18US032258 and 18US032738). No further medical information expected.<br>UPDATE 18 Jul 2018: The owner reported the following for Fluffy, a 9 year old, 8 pound, spayed female.<br>18 May 2018: 1 vial of the product was applied to the cat topically between the shoulder blades. This was the first application.<br>25 May 2018*: The cat vomited. The owner believes it was because the cat had fleas and was licking constantly. The cat recovered the same day.<br>The cat was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 30-May-2018 | UAE; 18US032738; OR; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 12 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 18-May-2018* | 18-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for a 12 pound, feline (all other signalments unknown).<br>18 May 2018: An unknown amount of FRONTLINE PLUS CATS (lot unknown) was given to the cat (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the cat vomited. It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. There were 2 other cats that had symptoms (see case 18US032258 and 18US032737). No further medical information expected.<br>UPDATE 18 Jul 2018: The owner reported this cat did not have any symptoms. |
| 05-Jun-2018 | UAE; 18US032838; KY; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 9 lbs | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | N/A | 07-May-2018 | 15 Day(s) | D-D | Suspected Adverse Event: On 31 May 2018, the owner reported the following event for two 9 pound, Chihuahuas (all other signalments unknown).<br>22 Apr 2018*: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (lo unknown) was given to each dog (unknown route and site of application), by the owner. The dogs are treated on a year round basis, but frequency of application and how long they have been on the product is unknown.<br>7 May 2018: The dogs started scratching. The owner found fleas. It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected. |
| 31-May-2018 | UAE; 18US032914; NJ; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** U **Sex qualifier:** | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products** | 28-May-2018 | 28-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 31 May 2018, the owner reported the following event for 2 Domestic Short hairs of unknown signalment.<br>28 May 2018: One vial of FRONTLINE PLUS CATS (R40202AW). The cats started vomiting which is still ongoing.<br>No further medical information available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | |
| 30-May-2018 | UAE; 18US032934; TX; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 90 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 07-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for Hank, a 90 pound, canine (all other signalments unknown).<br>7 May 2018*: An unknown amount of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) was given to the dog (unknown route and site of application), by the owner. The owner treats on a year round basis but it is unknown how long. On an unknown date after the application, the owner saw fleas on the dog and the dog was chewing on itself and bleeding.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. The re was another dog treated with the product that had symptoms (see case 18US032546). No further medical information expected. |
| 31-May-2018 | UAE; 18US032944; MI; U.S.A | **Species:** Canine<br>**Breed:** Schnauzer (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 12.5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 29-Apr-2018 | 29-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 30 May 2018, the owner reported the following event for Shadow a 4 year old, 12.5 pound, neutered male Schnauzer (Miniature).<br>29 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied to the dog. Immediately the owner noticed the dog stopped eating and drinking.<br>The dog has not been seen by the vet for her ongoing symptoms. The dog received FL the month prior with no issues. No further medical information available. |
| 01-Jun-2018 | UAE; 18US033086; VA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Mediumhair (Crossbred)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 15.00 Year(s)<br>**Weight:** 8 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** Zantac;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 27-May-2003 | 28-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 1 June 2018, the owner reported the following event for Puss, a 15 year old, 8 pound, neutered male Domestic Medium hair.<br>27 May 2018: One vial of FRONTLINE PLUS CATS (R40202) was applied per the label to the cat.<br>28 May 2018: The cat skin had bubbled up at the site of application.<br>The owner is monitoring the cat without vet assistance for his ongoing condition. The cat has been on FL for years with no issues. The has anxiety and takes Zantac and has not had any issues with this medication. No further medical information available. |
| 01-Jun-2018 | UAE; 18US033206; FL; U.S.A | **Species:** Canine<br>**Breed:** Bichon Frise<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 14 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | 01-May-2015* | 08-May-2018 | 1 Week(s) | D-D | Suspected Adverse Event: On 1 June 2018, the owner reported the following event for Chelsea, a 3 year old, 14 pound, spayed female Bichon Frise.<br>1 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P62719AL) was applied to the dog per label.<br>8 May 2018: The dog developed a yellow spot at the site of application.<br>4 June 2018: The spot is appearing to fade, but it is still apparent. The dog has been on FL all her life with no issues, she has not |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | been seen by the vet for her ongoing symptom. No further information available. |
| 01-Jun-2018 | UAE; 18US033241; -; U.S.A | **Species:** Canine<br>**Breed:** Bernese Mountain Dog<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 12.00 Month(s)<br>**Weight:** 70 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Otic<br>**Was the product used ok?:** No (Off label use / Indication) | 29-May-2018 | 30-May-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 31 May 2018, the following event was reported to Safety Call International (SCI) by the pet owner reported the following event for Poe, a 1 year old (born *21 May 2017), 70 pound, male neutered Bernese Mountain Dog mix.<br>29 May 2018: The pet owner applied 5 to 7 drops from 1 vial of FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown) into the left ear. The pet owner believed the dog had ear mites.<br>30 May 2018: The pet owner applied 5-7 drops of the product into the right ear. At an unknown time period following application the dog began exhibiting a right sided head tilt and twitching. There was an attempt made to cleanse the ear with Zymox. The dog presented to the clinic and upon exam there were no vestibular signs noted and both ear drums appeared intact. A infection was noted in the left ear. The current health status of the dog is unknown.<br>No further information is available at this time. |
| 01-Jun-2018 | UAE; 18US033298; MN; U.S.A | **Species:** Canine<br>**Breed:** Poodle (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Unknown Rabies vaccination; Unknown pain medication; Unknown pre-medication;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 17-May-2008* | 19-May-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 1 Jun 2018, the owner reported the following event for Iris, an approximately 10 year old, 10 pound, spayed female, Poodle (Miniature).<br>2008*: The dog started on 1 vial of FRONTLINE PLUS DOG 5-22 LBS (H67613) given to the dog topically between the shoulder blades, by the owner. The dog was treated monthly on a seasonal basis from approximately Apr-Oct.<br>10 May 2018: The dog was given an unknown pre-medication, unknown pain medication, and an unknown rabies vaccination.<br>17 May 2018: The dog was given another dose of FRONTLINE PLUS DOG 5-22 LBS.<br>19-20 May 2018: the dog started vomiting.<br>21-23 May 2018: The dog had diarrhea.<br>23 May 2018: The dog recovered.<br>The dog was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 04-Jun-2018 | UAE; 18US033405; IL; U.S.A | **Species:** Canine<br>**Breed:** Akita<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Month(s)<br>**Weight:** 47.5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** AFOXOLANER 136 MG CHEWABLE TABLETS; cephalexin;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 15-Mar-2018 | 19-Mar-2018 | 4 Day(s) | D-C | Suspected Adverse Event: On 4 Jun 2018, a clinic staff reported the following event for Bruno, a 6 month old (15 Sep 2017, 47.5 pound, neutered male Akita.<br>15 Mar 2018: 1 vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulders for the first time.<br>19 Mar 2018: The dog had flaky skin, crusting, pustules, and pruritus over the area of application over the dorsum. The dog presented to the clinic and a skin scrape was performed and the owner was instructed to bathe the dog with an unknown shampoo.<br>26 Mar 2018: The dog was prescribed chlorhexidine shampoo.<br>2 Apr 2018: The dog was prescribed cephalexin due to continued symptoms.<br>12 Apr 2018: The dog symptoms had improved and cephalexin was stopped.<br>15 Apr 2018: The 54.8 pound dog was started on 1 chew of NEXGARD (68 MG) (lot and expiration unknown) for the first time.<br>16 Apr 2018: The dog's symptoms became progressively worse and pyoderma was seen in the inguinal region. A skin biopsy was |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | performed and revealed severe acute pyoderma and underlying allergic skin disease. The dog was again prescribed cephalexin, continued on chlorhexidine shampoo, and started on Dermoscent.<br>17 Apr 2018*: Bruno appetite decreased. The veterinarian suspected the decrease in appetite was due to cephalexin, but the symptoms were not seen when cephalexin was first prescribed.<br>17 May 2018: 1 chew of NEXGARD (136 MG) (lot and expiration unknown) was given to the 60 pound canine. The dog's skin issues had improved.<br>There have bee no further updates from the pet owner on the dog's status. Bruno has a history of flaky skin since 20 Feb 2018. No further information available. |
| 06-Jun-2018 | UAE; 18US033700; OH; U.S.A | **Species:** Canine<br>**Breed:** Shar Pei<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 30-May-2017* | 30-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 4 June 2018, the owner reported the following event for a Shar Pei (signalment unknown).<br>30 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201AR) was applied to the dog.<br>On an unknown date the dog had some sensitivity, No further medial information available. |
| 04-Jun-2018 | UAE; 18US033702; NE; U.S.A | **Species:** Canine<br>**Breed:** Bichon Frise<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 19.9 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Prednisone;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2010* | 01-Jun-2018 | 4 Day(s) | D-D | Suspected Adverse Event: On 4 Jun 2018, the owner reported the following event for Princess, an 8 year old, 19.9 pound, spayed female, Bichon Frise.<br>2010*: The dog started on 1 vial of FRONTLINE PLUS DOG 0-22 LBS (lot unknown) given to the dog topically between the shoulder blades, by the owner. The frequency of application is unknown.<br>24 May 2018: The dog started on Prednisone.<br>28 May 2018*: The dog was given another dose of Frontline Plus.<br>29 May 2018: The dog got the last dose of Prednisone.<br>1 Jun 2018: The fur at the application site turned yellow. There was no skin irritation.<br>The dog was seen by the veterinarian but was not given any treatment. The symptoms are ongoing. The dog is groomed regularly. The dog has a history of allergies. No further medical information expected. |
| 04-Jun-2018 | UAE; 18US033740; WA; U.S.A | **Species:** Canine<br>**Breed:** Dachshund<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 22 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Overdose) | 27-May-2009* | 27-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 4 Jun 2018, the owner reported the following event for Pepper, a 10 year old, 22 pound, neutered male, Dachshund.<br>2009*: The dog started on 1 vial of FRONTLINE PLUS 5-22 LBS (lot unknown) given to the dog topically between the shoulder blades, by the owner.<br>27 May 2018: The dog was given 1 vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown). The dog started itching and biting and pulling out fur.<br>1 Jun 2018: The owner bathed the dog and the symptoms stopped. The dog was not seen by the veterinarian. No further medical information expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 04-Jun-2018 | UAE; 18US033780; PA; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** - **Weight:** 6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 03-Jun-2017 | 03-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 4 June 2018, the owner reported the following event for Grace, a 6 pound, spayed female Domestic Shorthair.<br>3 June 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was topically applied to the cat. Immediately after the application the cat started to foam at the mouth and shake a little bit. The cat also hid and did not eat or drink yesterday, but eventually she did . The cat has has FL in the past with no issues. There is one other treated cat in the home. See case 18US034507. No further information available. |
| 04-Jun-2018 | UAE; 18US033791; PA; U.S.A | **Species:** Canine **Breed:** Spaniel (Cocker) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 04-Mar-2018* | 04-Mar-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 4 June 2018, the owner reported the following event for a male Spaniel (Cocker) (signalment unknown).<br>*4 March 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was topically treated to the dog. Within a half hour the dog became paranoid, went off by himself in a corner, and was looking at the owner as if they were going to hurt him.<br>No further information available. |
| 05-Jun-2018 | UAE; 18US033907; MA; U.S.A | **Species:** Canine **Breed:** Retriever (Labrador, Black) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 52 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 26-Apr-2018 | 29-May-2018 | 3 Day(s) | D-C | Suspected Adverse Event: On 5 June 2018, the owner reported the following event for Penny, 4 year old, 52 pound, spayed female, Black Labrador Retriever mix canine.<br>26 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (P60604AR) was applied between the shoulder blades.<br>29 May 2018: The pet experienced a seizure lasting 4-5 minutes then recovered. The pet was presented to the clinic and no treatment was provided. The pet recovered.<br>The pet has previously reacted to the Seresto Collar in the past.<br>No further medical information is expected. |
| 05-Jun-2018 | UAE; 18US033935; CA; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 20 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 02-Jun-2018 | 02-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 5 June 2018, the owner reported the following event for CiCi, a 3 year old, 20 pound, neutered male cat (breed unknown by owner).<br>2 June 2018: The cat had fleas and one vial of FRONTLINE PLUS CATS (R40601AW) was topically applied per the label for the first time. Fifteen minutes after the treatment the cat was scratching more.<br>The cat has not been seen by the vet and the owner is monitoring the cat's symptoms. There are three other cat in the home, see cases 18US034170 and 18US34168. No further information available.<br>26 June 2018: UPDATE : Per the owner the cat's symtpoms are still ongoing. Everytime the cat wake up its itching and biting themselves and onto the stomach and legs. No further medical |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | information available. |
| 05-Jun-2018 | UAE; 18US033947; MO; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 05-May-2018 | 05-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 5 Jun 2018 , the owner reported the following event for Bailee, 2 year old, 10 pound, spayed female, Chihuahua canine.<br>5 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60525AL) was applied between the shoulder blades. The dog experienced slight skin irritation.<br>Unknown date: The dog recovered.<br>5 Jun 2018: Another vial was applied. The dog experienced skin irritation. Immediately after the dog began running around like the product was burning. The owner bathed the dog and she recovered. The pet was not presented to the clinic.<br>No further medical information is expected. |
| 05-Jun-2018 | UAE; 18US033958; PA; U.S.A | **Species:** Canine **Breed:** German Shepherd Dog **Sex:** M **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 124 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Aug-2012 | 15-Aug-2012* | N/A | D-B | Suspected Adverse Event: On 5 June 2018, the owner reported the following event for Balathazar, a 9 year old, 124 pound, neutered male German Shepherd.<br>*1 Aug 2012: One vial of FRONTLINE PLUS DOG 89-132 LBS (FL) (lot unknown) was topically applied per the label.<br>Within a few weeks the dog had sporadic seizures, the dog continued to be treated with FL monthly and continued to have sporadic seizures. The dog was seen by the vet and placed on Potassium Bromide. The dog stopped receiving FL in Aug 2017 and did not have anymore seizures once the product was stopped.<br>No further information available. |
| 05-Jun-2018 | UAE; 18US033990; MO; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 15 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-May-2008* | 15-May-2018* | 2 Week(s) | D-D | Suspected Adverse Event: On 5 June 2018, the owner reported the following event for Scooter, a 10 year old 15 pound, neutered male Domestic Shorthair.<br>1 May 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was topically applied to the cat per label.<br>*15 May 2018: The cat developed a blister and hairloss at the application site.<br>The cat has been on FL all his life with no issues and the owner is monitoring his ongoing symptoms without vet assistance. There is one other treated cat in the home, see case 18US034191. No further information available. |
| 05-Jun-2018 | UAE; 18US033999; WI; U.S.A | **Species:** Canine **Breed:** American Bully **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 80 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination | 01-Jan-2015 | 02-May-2018 | 8 Day(s) | D-D | Suspected Adverse Event: On 5 Jun 2018, a veterinary technician reported the following event for Reuben, a 10 year old (born 1 Sep 2007), 80 pound, male neutered American Bulldog.<br>24 Apr 2018: The owner applied FRONTLINE PLUS DOG 45-88 LBS (lot unknown) and the owner applied topically between the shoulder blades.<br>30 Apr 2018: The owner emailed the clinic stating the dog had sores on the back of neck and the sores were not everywhere the product was applied. The dog also had hair loss in some areas.<br>7 May 2018: The dog presented for laser therapy and the DVM prescribed Simplicef.<br>21 May 2018: The owner stated the area was getting worse and the DVM offered for the dog to be seen again but the owner declined.<br>The dog's current status is unknown. No further medical |

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| | | | | | | program not respected) | | | | | information expected.<br>Update 18 Jun 2018: The email from the owner to the clinic, dated 02 May 2018, stated Frontline Plus was administered in a line from the base of his skull to the top of his back. The sores and hair loss occurred on a portion of the application site. |
| 05-Jun-2018 | UAE; 18US034008; WY; U.S.A | **Species:** Canine<br>**Breed:** Collie<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 9.00 Year(s)<br>**Weight:** 65 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Rimadyl; Endosorb; Dasuquin;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 03-Jun-2017 | 04-Jun-2018* | 1 Day(s)* | D-D | Suspected Adverse Event: On 5 June 2018, the owner reported the following event for Chrisin, a 9 year old 65 pound, neutered male Collie.<br>3 Jun 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (P62104AR) was topically applied per label to the dog.<br>*4 June 2018: The dog would not eat, he was lethargic, vomiting, eating grass, and waking up in the middle of the night.<br>The dog has not been seen by the vet for his ongoing symptoms. The dog has arthritis and takes Rimadyl, the dog also takes Dasuquin and Endosorb. No further medical information available. |
| 05-Jun-2018 | UAE; 18US034059; MO; U.S.A | **Species:** Canine<br>**Breed:** Terrier (Jack Russell)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 05-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 5 Jun 2018, the owner reported the following event for a Jack Russell Terrier canine (all other signalments unknown).<br>Unknown date: An unknown amount of FRONTLINE PLUS DOG 23-44 LBS (R61915AL) was applied to the dog. The dog began scratching and chewing his skin raw. It is unknown if the pet was presented to the clinic or if any treatment was provided.<br>No further medical information is expected. |
| 05-Jun-2018 | UAE; 18US034069; WA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 13 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jun-2011* | 03-Jun-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 5 Jun 2018, the owner reported the following event for Dominic, 7 year old, 13 pound, neutered male, Domestic Shorthair feline.<br>1 Jun 2018: One vial of FRONTLINE PLUS CATS (R40801) was applied between the shoulder blades.<br>3 Jun 2018: The cat experienced lethargy. The pet was not presented to the clinic. The owner bathed the pet.<br>5 Jun 2018: Symptoms have improved but are still ongoing.<br>The cat has received FRONTLINE seasonally since 1 Jun 2011* and no symptoms presented. No further medical information is expected. |
| 05-Jun-2018 | UAE; 18US034097; -; U.S.A | **Species:** Canine<br>**Breed:** Pointer (German Wire-Haired)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 1.00 Year(s)<br>**Weight:** 67 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | N/A | 09-May-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 5 Jun 2018, the veterinarian reported the following event for Winnie, 1 year old, 67 pound, spayed female, German Wire- Haired Pointer canine.<br>9 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades. After a few hours the dog experienced a seizure lasting 1 minute. The dog also presented aggression during the episode. The dog recovered.<br>10 May 2018: The pet was presented to the clinic and no treatment was provided. |

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| | | | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | The dog has received the product before on an unknown date and no symptoms presented. No further medical information is expected. |
| 05-Jun-2018 | UAE; 18US034114; NJ; U.S.A | **Species:** Canine<br>**Breed:** French Bulldog<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 12.00 Year(s)<br>**Weight:** 18.9 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 03-Jun-2018 | 04-Jun-2018 | 1 Day(s) | D-C | Suspected Adverse Event: On 4 Jun 2018, the following event was reported to Safety Call International (SCI) by the clinic staff for Bling, an 18.9 pound, *12 year old, spayed female, French Bulldog.<br>3 Jun 2018: Bling received a dose of FRONTLINE PLUS DOG 23-44 LBS(lot unknown) at 5:00pm.<br>4 Jun 2018: The pet owner reported that the dog became lethargic and had labored breathing. Bling presented to the clinic where laboratory work was performed with unknown results.<br>It is unknown if Bling has received the FRONTLINE PLUS in the past or if she has any history of drug or vaccine reactions. Bling does have a history of labored breathing. No further information at this time. |
| 05-Jun-2018 | UAE; 18US034168; CA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 10.00 Week(s)<br>**Weight:** 2 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 02-Jun-2018 | 02-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 5 June 2018, the owner reported the following event for Rascal, a 10 week old, 2 pound, intact female cat (breed unknown by owner).<br>2 June 2018: The cat had fleas and one vial of FRONTLINE PLUS CATS (R40601AW) was topically applied per the label for the first time. Fifteen minutes after the treatment the cat was scratching more.<br>The cat has not been seen by the vet and the owner is monitoring the cat's symptoms. There are three other cat in the home, see cases 18US033935 and 18US034170. No further information available.<br>26 June 2018: UPDATE : Per the owner the cat's symtpoms are still ongoing. Everytime the cat wake up they're itching and biting themselves and onto the stomach and legs. No further medical information available. |
| 05-Jun-2018 | UAE; 18US034170; CA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 2.00 Year(s)<br>**Weight:** 12 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 02-Jun-2018 | 02-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 5 June 2018, the owner reported the following event for Boots, a 2 year old, 12 pound, spayed female cat (breed unknown by owner).<br>2 June 2018: The cat had fleas and one vial of FRONTLINE PLUS CATS (R40601AW) was topically applied per the label for the first time. Fifteen minutes after the treatment the cat was scratching more.<br>The cat has not been seen by the vet and the owner is monitoring the cat's symptoms. There are three other cat in the home, see cases 18US034168 and 18US033935. No further information available.<br>26 June 2018: UPDATE : Per the owner the cat's symtpoms are still ongoing. Everytime the cat wake up its itching and biting themselves and onto the stomach and legs. No further medical information available. |
| 05-Jun-2018 | UAE; 18US034191; MO; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other | 01-May-2008 | 15-May-2018* | 2 Week(s) | D-D | Suspected Adverse Event: On 5 June 2018, the owner reported the following event for Tater, a 1.5 year year old, 12 pound, spayed female Domestic Shorthair.<br>1 May 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was topically applied to the cat per label.<br>*15 May 2018: The cat developed a blister and hairloss at the application site. |

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| | | **Age:** 1.50 Year(s)<br>**Weight:** 12 lbs | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | The cat has been on FL all her life with no issues and the owner is monitoring his ongoing symptoms without vet assistance. There is one other treated cat in the home, see case 18US033990. No further information available. |
| 03-Jun-2018 | UAE; 18US034207; PA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 16.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** Hartz Ultraguard Plus;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 01-Feb-2018* | 17 Day(s) | D-B | Suspected Adverse Event: On 3 Jun 2018, the following inquiry was reported to Safety Call International (SCI) by the pet owner for Elsie, a 16 year old, spayed female, indoor/outdoor, Domestic Shorthair of further unknown signalment.<br>Unknown dates: Per the reporter, an unknown time ago, a Hartz Ultraguard Plus collar was placed on Elsie and every time she wore it, she experienced alopecia.<br>Unknown dates: Although neither a date nor duration can be confirmed, it seems that on a subsequent date after receiving the Hartz Ultraguard Plus collar, the reporter applied an unknown amount of FRONTLINE PLUS CATS (R401108W) (invalid lot), topically, in an unknown location on the patient. An unknown date post FRONTLINE PLUS CATS application, Elsie developed a large oral mass which the pet owner states her veterinarian suspects is cancerous; however, a biopsy has not been performed. It cannot be confirmed if any therapies were administered at any point for the reported oral mass. At the time the pet owner reported the event to SCI, Elsie was alive with sequelae; she was scheduled to be euthanized the following day according to the pet owner, but ultimately, her current status remains unknown. There are at least two other cats in the home, but it's unknown if they received the reported products. A human exposure involving the pet owner and the reported lot of FRONTLINE PLUS CATS was also reported. Please see case 18US034151. No further medical information expected. |
| 06-Jun-2018 | UAE; 18US034210; WI; U.S.A | **Species:** Feline<br>**Breed:** Russian Blue<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 12 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Sep-2014 | 05-Jun-2018 | 6 Day(s) | D-D | Suspected Adverse Event: On 6 Jun 2018, the owner reported the following event for Rugby, 4 year old, 12 pound, neutered male, Russian Blue feline.<br>30 May 2018: One vial of FRONTLINE PLUS CATS (R40719) was applied between the shoulder blades.<br>5 Jun 2018: The cat experienced hair loss at the application site. The pet was not presented to the clinic and no treatment was provided.<br>7 Jun 2018: Symptoms are still ongoing.<br>No further medical information is expected. |
| 06-Jun-2018 | UAE; 18US034219; FL; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Labrador, Yellow)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 70 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | N/A | 21-May-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 6 Jun 2018, the owner reported the following event for a 70 pound, Retriever (Labrador, Yellow) (all other signalments unknown).<br>Unknown Date: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (R60601BR) was given to the dog topically (unknown site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the dog had patchiness and irritation (scab) near the neck/shoulder area. The dog was seen by the veterinarian but it is unknown if it was given any treatment. The dog's current status is unknown. No further medical information expected.<br>UPDATE 8 Jun 2018 NH: The owner reported the following event |

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| | | | | | | **ok?:** Yes | | | | | for Dixie, 4 year old, spayed female.<br>19 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R60601BR) was applied between the shoulder blade.<br>21 May 2018: The pet experienced irritation at the application site.<br>24 May 2018: The pet was presented to the clinic. The attending veterinarian provided treatments unknown to the pet owner.<br>8 Jun 2018: Symptoms have improved significantly but are still ongoing.<br>The dog has received the product on prior unknown date and no symptoms presented. No further medical information expected. |
| 06-Jun-2018 | UAE; 18US034252; NH; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 50 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 02-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 6 Jun 2018, the nurse reported the following event for a canine (all other signalments unknown).<br>1 Jun 2018: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (R61201CR) was applied at an unknown location.<br>2 Jun 2018: The dog experienced lethargy and strange behavior. It is unknown if the pet was presented to the clinic. The owner bathed the pet. The status of the pet is unknown.<br>No further medical information is expected. |
| 06-Jun-2018 | UAE; 18US034352; IA; U.S.A | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 7.5 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 05-Jun-2018 | 05-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 6 Jun 2018, the owner reported the following event for Kirby, a 5 year old, 7.5 pound, neutered male, Yorkshire Terrier/Bichon Frise mixed breed.<br>5 Jun 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (P62408AL) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied. Within about an hour the dog was itching and was warm to the touch.<br>The dog was not seen by the veterinarian. The owner gave the dog a bath. The symptoms are ongoing. No fleas have been observed.<br>No further medical information expected. |
| 08-Jun-2018 | UAE; 18US034419; CA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 13 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | N/A | 05-Jun-2018 | 11 Day(s) | D-D | Suspected Adverse Event: On 6 Jun 2018, the owner reported the following event for a 13 pound, feline (all other signalments unknown).<br>25 May 2018: An unknown amount of FRONTLINE PLUS CATS (lot unknown) was given to the cat (unknown route and site of application), by the owner. The cat has been treated on a year round basis for an unknown amount of time. The owner may have seen a flea on the cat.<br>5 Jun 2018: The owner noticed the cat scratching.<br>It is unknown if the cat was seen by the veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected. |
| 06-Jun-2018 | UAE; 18US034429; WI; U.S.A | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** M<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | N/A | 05-Jun-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 6 Jun 2018, the owner reported the following event for a 12 pound, male, Yorkshire Terrier (all other signalments unknown).<br>5 May 2018: The dog received a dose of HEARTGARD PLUS (68 MCG/57 MG) (lot unknown, expiration unknown, product |

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| | | Unknown<br>**Age:** -<br>**Weight:** 12 lbs | | | | **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | unsubstantiated). The dog has been on the product before for an unknown amount of time.<br>5 Jun 2018: 1 dose of FRONTLINE (lot unknown, product unsubstantiated) was given to the dog topically between the shoulder blades, by the owner. The dog has been on the product before for an unknown amount of time. Approximately 4.5 hours later, the dog had a neurologic event. The dog was shaking, walking robotically, and bit his tongue. The symptoms lasted about 15-20 seconds.<br>The dog was seen by the veterinarian but was not given any treatment. No further medical information expected. |
| 06-Jun-2018 | UAE; 18US034466; PA; U.S.A | **Species:** Canine<br>**Breed:** Pomeranian<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 9.00 Year(s)<br>**Weight:** 8 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** AFOXOLANER 11.3 MG CHEWABLE TABLETS; Termaril-P; Amoxicillin; IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Nov-2008* | 23-May-2018 | 3 Week(s) | D-C | Suspected Adverse Event: On 6 Jun 2018, the manager reported the following event for Chewy, a 9 year old (born 25 Aug 2008) 8 pound male neutered Pomeranian.<br>2 Jun 2018: The dog was given a dose of NEXGARD (11.3 mg) (lot and expiration unknown) for the first time.<br>6 Jun 2018: The dog experience vomiting with blood and bloody diarrhea and presented to the clinic. The clinic performed a CBC/Chemistry, which is pending.<br>The dog's status was the same at the time of the phone call and was at the clinic for treatment. The dog has a history of vomiting after unknown vaccines. No further medical information expected.<br>UPDATE 7 Jun 2018: Via the medical records on 5 Jun 2018, the dog was slightly lethargic, not wanting to eat, was panting heavily, and breathing seems labored. The dog was also given Termerial P and Amoxicillin for a URI on an unknown date. It is unknown if that was prior to the NEXGARD.<br>6 Jun 2018: The clinic performed a CBC/Chemistry with the abnormal results as follows: Crea 0.3 (0.5-1.8), ALT 141 (10-125), ALKP 336 (23-212), AMYL 365 (500-1500), BANDS suspected, and EOS 0.06 (0.05-1.23). They also performed unknown radiographs with unknown results. The treated with Metronidazole, Cerenia, and Hepatp TruBenefits.<br>The dog's current status is unknown. No further medical information expected.<br>UPDATE 8 Jun 2018: Per the office manager:<br>2008 (unknown dates): The patient began receiving one chew of HEARTGARD PLUS (68 MCG/57 MG) (lot and expiration unknown), PO, and one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown), applied topically, in an unknown location.<br>2 May 2018*: FRONTLINE PLUS was applied.<br>23 May 2018: Chewy presented to the veterinarian with a suspected upper respiratory infection (URI). A 4Dx test was negative and the abnormalities on a CBC/Chem performed included the following: BUN 35 (7-27), and HCT 51 (14-46). The patient subsequently was treated with I/D (diet), as well as ten day courses of Temaril-P and amoxicillin.<br>1 Jun |
| 06-Jun-2018 | UAE; 18US034487; WA; U.S.A | **Species:** Canine<br>**Breed:** Maltese<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other | N/A | 06-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 6 Jun 2018, the owner reported the following event for a Maltese mix canine (all other signalments unknown).<br>Unknown date: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades. The pet experienced increased itching. It is unknown if the was presented to the clinic or if any treatment was provided. The status of the pet |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | is unknown.<br>There is one other dog in the household that also received FRONTLINE and is asymptomatic. No further medical information is expected. |
| 04-Jun-2018 | UAE; 18US034507; PA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 03-Jun-2017 | 03-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 4 June 2018, the owner reported the following event for male cat (signalment unknown).<br>3 June 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was topically applied to the cat. The cat became lethargic for a few hours and recovered<br>The cat has has FL in the past with no issues. There is one other treated cat in the home. See case 18US033780. No further information available. |
| 05-Jun-2018 | UAE; 18US034516; -; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 04-Jun-2018* | 04-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 5 Jun 2018 the pet owner reported the following adverse event via email for an unknown female canine of unknown signalment.<br>4 Jun 2018*: The dog received an unknown FRONTLINE brand product (lot and expiration unknown) (product unsubstantiated) route, amount, and location are unknown.<br>5 Jun 2018: Within hours of application at approximately 3 AM the dog developed explosive diarrhea. It is unknown if the pet presented to a clinic or if treatment has been provided.<br>It is unknown if the pet has received FRONTLINE previously. No further information is expected. |
| 05-Jun-2018 | UAE; 18US034579; NJ; U.S.A | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 03-Jun-2017* | 03-Jun-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 5 June 2018, the owner's aunt reported the following event for a Chihuahua of unknown signalment.<br>*3 June 2017: One vial of FRONTLINE (lot unknown) (product unsubstantiated).<br>Following the treatment the dog started shaking on an unknown date.<br>The dog had the same reaction with NEXGARD (28.3 mg) (AA106517A , Jan 2019) , see case 18US034047. No further information available. |
| 07-Jun-2018 | UAE; 18US034782; FL; U.S.A | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 2.50 Year(s)<br>**Weight:** 11 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products | 07-Oct-2015 | 07-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 7 June 2018, the owner reported the following event for Stewart, a 2.5 year old, 11 pound, neutered male Shih Tzu.<br>7 June 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60525AL) was applied per label to the dog and following the treatment the dog's fur turned pink.<br>The dog has been on FL all his life with no issues. No further medical information available. |

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| | | | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | |
| 07-Jun-2018 | UAE; 18US034828; PA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 07-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 7 Jun 2018, the owner reported the following event for a Domestic Shorthair feline.<br>Unknown date: An unknown amount of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. The cat experienced hair loss on the back of the head. It is unknown if the pet was presented to the clinic or if any treatment was provided.<br>The status of the cat is unknown.<br>No further medical information is expected. |
| 07-Jun-2018 | UAE; 18US034873; TX; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 28-Apr-2018 | 07-Jun-2018* | 13 Day(s) | D-D | Suspected Adverse Event: On 7 Jun 2018, the owner reported the following event for a canine.<br>28 Apr 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was applied between the shoulder blades.<br>25 May 2018: Another vial was applied.<br>Unknown date: The pet experienced itching. It is unknown if the pet was presented to the clinic or if any treatment was provided.<br>The status of the pet is unknown.<br>The pet has recceived the product on prior unknown dates it is unknown if any symptoms presented. No further medical information is expected. |
| 07-Jun-2018 | UAE; 18US034884; NE; U.S.A | **Species:** Canine<br>**Breed:** German Shepherd Dog<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 1.50 Year(s)<br>**Weight:** 90 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Cosequin;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Low dose) | 02-Jun-2018 | 07-Jun-2018 | 5 Day(s) | D-D | Suspected Adverse Event: On 7 Jun 2018, the owner reported the following event for Prince, a 1.5 year old, 90 pound, neutered male, German Shepherd Dog.<br>Jan 2018*: The dog started on Cosequin.<br>2 Jun 2018: 1 dose of FRONTLINE PLUS DOG 45-88 LBS (R61811AR) was given to the dog topically between the shoulder blades. This was the first application of the product. The dog also received Cosequin.<br>7 Jun 2018: The owner noticed a hotspot about 8 inches long and 4 inches across at the site of application.<br>The dog was seen by a veterinarian and given Amoxicillin and prednisone. The symptoms are ongoing. No further medical information expected. |
| 07-Jun-2018 | UAE; 18US034959; GA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Mediumhair (Crossbred)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 15.00 Month(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | 05-Jun-2018 | 07-Jun-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 7 June 2018, the owner reported the following event for Tuffy, a 15 month old, neutered male Domestic Mediumhair.<br>5 June 2018: The cat was treated with one vial of FRONTLINE PLUS CATS (R41212AW) per label for the first time.<br>7 June 2018: The cat started pulling out his fur, had diarrhea, and developed irritation at the application site.<br>The owner is monitoring the cat's condition and the cat has not been seen by the vet. No further medical information available. |

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| | | **Weight:** Unknown | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | |
| 07-Jun-2018 | UAE; 18US034984; WA; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2018* | 01-Jun-2018* | 0 Day(s) | D-B | Suspected Adverse Event: On 7 Jun 2018, a veterinary technician reported the following event for a canine of unknown signalment.<br>Unknown Dates: The dog has been received FRONTLINE PLUS DOG (product unsubstantiated)(lot unknown) for an unknown amount of time.<br>Unknown Date: The dog developed liver and kidney failure. It is unknown if treatment has been given. No further medical information expected. |
| 07-Jun-2018 | UAE; 18US035000; MN; U.S.A | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 65 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 04-Jun-2013* | 07-Jun-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 7 June 2018, the owner reported the following event for Bear, a 5 year old, 65 pound, spayed female Retriever.<br>4 June 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (M64001AR) was topically applied to the dog per the label.<br>7 June 2018: The dog's fur turned gold at the application site.<br>The dog has been on FL all her life with no issues. The dog has not been seen by the vet for her ongoing symptoms. No further medical information available. |
| 07-Jun-2018 | UAE; 18US035001; CA; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Labrador, Yellow)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 11.00 Year(s)<br>**Weight:** 66 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 24-May-2009* | 27-May-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 7 Jun 2018, the owner reported the following event for a Retriever (Golden) (all other signalments unknown).<br>24 May 2018*: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (R61811AR) was given to the dog (unknown route, and site of application), by the owner. It is unknown if this was the first dose applied.<br>27 May 2018*: The dog had a scab at the application site.<br>It is unknown if the dog was seen by the veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected.<br>UPDATE 18 Jun 2018: The reported the following for Lexi, an 11 year old, approximately 66 pound, spayed female, Retriever (Labrador, Yellow).<br>2009*: The dog started on the product and was treated every 2 months, seasonally, from Mar-Aug<br>24 May 2018*: 1 vial of the product was applied to the dog topically between the shoulder blades.<br>The dog was not seen by the veterinarian or given any treatment.<br>The symptoms are ongoing. No further medical information expected. |
| 08-Jun-2018 | UAE; 18US035033; IA; U.S.A | **Species:** Canine<br>**Breed:** Pinscher (Miniature)<br>**Sex:** M | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | 08-Jun-2018* | 08-Jun-2018* | 0 Day(s) | D-C | Suspected Adverse Event: On 8 June 2018, the owner reported the following event for a male Pinscher (Miniature) (signalment unknown)<br>*8 June 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS |

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| | | **Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** Unknown | | | | 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | (R61020AL) was applied to the dog. Following the treatment the dog was lethargic, ataxic, he had runny stool, he wasn't acting normal, and he was not eating.<br>No further medical information available. |
| 08-Jun-2018 | UAE; 18US035035; ME; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 12 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2013* | 08-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 8 Jun 2018, the owner reported via email the following event for a feline of unknown signalment.<br>2018*: Cat received application of FRONTLINE PLUS CATS (lot number unknown) and it burned the cat's skin. No further information at this time.<br>UPDATE 8 Jun 2018: According to the pet owner, Alta is a 7 year old 12 pound male neutered Domestic Shorthair.<br>8 May 2018: The pet owner applied the dose topically between the shoulder blades down to the skin. Later that day, the cat started to lose hair at the application site.<br>10 May 2018*: The cat had a wound at the application site.<br>16 May 2018*: The wound healed.<br>The cat has been on FRONLTLINE for an unknown number for years without issue. No further medical information expected. |
| 08-Jun-2018 | UAE; 18US035041; TX; U.S.A | **Species:** Feline<br>**Breed:** Persian (No Further Description)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 7 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 04-Jun-2018 | 06-Jun-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 8 June 2018, the owner reported the following event for spayed female Persian.<br>4 June 2018: One vial of FRONTLINE PLUS CATS (R40515AW) was topically applied to the cat for the first time.<br>6 June 2018: The cat developed hair loss and skin irritation at the application site. The cat was bathrd and the owner is monitoring her condition without vet assistance.<br>No further medical information available. |
| 08-Jun-2018 | UAE; 18US035042; VA; U.S.A | **Species:** Canine<br>**Breed:** Pit Bull<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 2.00 Year(s)<br>**Weight:** 55 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 13-May-2018 | 16-May-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 8 Jun 2018 the owner reported the following event for Chance, 2 year old, 55 pound, neutered male, Pit Bull canine.<br>13 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (P61101AR) was applied between the shoulder blades.<br>16 May 2018: The dog experienced hair loss and irritation at the application site.<br>The dog was presented to the clinic. The attending veterinarian prescribed unknown medications.<br>8 Jun 2018: The pet recovered.<br>No further medical information is expected. |
| 08-Jun-2018 | UAE; 18US035070; PA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON | 11-Apr-2018* | 11-Apr-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 8 June 2018, the owner reported the following event for Blackie, a 3 pound cat (signalment unknown)<br>*11 April 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was topically applied to the cat. |

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| | | Unknown<br>**Age:** -<br>**Weight:** 3 lbs | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | On an unknown date the cat's fur fell out at the application site.<br>The owner declined the report, no further medical information available. |
| 08-Jun-2018 | UAE; 18US035146; NJ; U.S.A | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 8 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Apr-2018 | 20-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 8 Jun 2018, the owner reported the following event for Lucy, an 8 pound, female, Shih Tzu (all other signalments unknown).<br>20 Apr 2018: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (R60525AL) was given to the dog topically (unknown site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date following the application, the dog rolling around on the floor and pacing back and forth panting. The dog vomited and had diarrhea.<br>The dog was seen by a veterinarian and given Subcutaneous fluids, Cerenia, and Fortiflora. The dog's current status is unknown. There was another dog treated that had symptoms (see case 18US035152). No further medical information expected.<br>UPDATE 11 Jun 2018: The owner reported the following for a 3 year old, spayed female.<br>20 Apr 2018: The dog received 1 vial of the product. This was the first dose applied. The symptoms started the same day.<br>26 Apr 2018: The dog recovered.<br>No further medical information expected. |
| 08-Jun-2018 | UAE; 18US035152; NJ; U.S.A | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 1.50 Year(s)<br>**Weight:** 11 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 20-Apr-2018 | 20-Apr-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 8 Jun 2018, the owner reported the following event for Tara, an 11 pound, female, Shih Tzu (all other signalments unknown).<br>20 Apr 2018: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (R60525AL) was given to the dog topically (unknown site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date following the application, the dog became " lucid" and eyes were very heavy and low. The dog vomited and had diarrhea.<br>The dog was seen by a veterinarian and given Subcutaneous fluids and Cerenia. The dog's current status is unknown. There was another dog treated that had symptoms (see case 18US035146). No further medical information expected.<br>UPDATE 11 Jun 2018: The owner reported the following for a 1.5 year old, spayed female.<br>20 Apr 2018: The dog received 1 vial of the product. This was the first dose applied. The symptoms started the same day.<br>The symptoms are ongoing. No further medical information expected. |
| 08-Jun-2018 | UAE; 18US035161; NC; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 12.4 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | 19-Apr-2018 | 20-Apr-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 8 June 2018, the pet owner reported the following event for Oskar, an 8 year old, 12.4 pound, neutered male Domestic Shorthair.<br>19 April 2018: One vial of FRONTLINE PLUS CATS (R40110AW) was applied to the cat for the first time.<br>20 April 2018: The cat developed skin irritation and hair loss at the application site.<br>30 May 2018: The cat was seen by the vet and given an antibiotic shot and Seresto collar . |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | 1 June 2018: The cat ran away.<br>No further medical information available. |
| 08-Jun-2018 | UAE; 18US035195; KS; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 3 | 3 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Jun-2018* | 01-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 8 June 2018, the company representative reported the following event for three Domestic Short hairs (further signalment unknown).<br>1 June 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was topically applied to the cats.<br>On an unknown date, the cats developed skin irritation and hair loss at the application. The cats were given an unknown antibiotic to help offer relief. No further medical information available. |
| 08-Jun-2018 | UAE; 18US035282; -; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2018* | 01-Jan-2018* | 0 Day(s) | D-C | Suspected Adverse Event: On 8 Jun 2018, the veterinarian reported the following event for a canine (all signalments unknown).<br>Unknown Date: An unknown amount of FRONTLINE (lot unknown, product unsubstantiated) was given to the dog (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the dog had a 3x4 inch area in an unknown location that, when pinch, caused extreme pain. The dog also had a temperature of 104.1 degrees Fahrenheit.<br>The dog was seen by the veterinarian but it is unknown what treatment was given. The dog's current status is unknown. No further medical information expected. |
| 08-Jun-2018 | UAE; 18US035337; OK; U.S.A | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Off label use / Indication) | N/A | 08-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 8 Jun 2018, the owner reported the following event for a Chihuahua canine (all other signalments unknown).<br>7 Jun 2018: One vial of FRONTLINE PLUS CATS (R40202AW) was applied between the shoulder blades.<br>8 Jun 2018: The pet became very sluggish and feverish. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 08-Jun-2018 | UAE; 18US035373; OK; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 15 lbs | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | 08-Jun-2018 | 08-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 8 June 2018, the owner reported the following event for Cami, a 6 year old 15 pound, spayed female Domestic Shorthair.<br>8 June 2018: One vial of FRONTLINE PLUS CATS (R41105AW) was applied per label to the cat. Two minutes later the cat started to drool.<br>The cat had the same reaction using a flea spray in the past. There are to other treated cats in the home who did not have a reaction.<br>No further medical information available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | |
| 11-Jun-2018 | UAE; 18US035431; PA; U.S.A | **Species:** Equine<br>**Breed:** -<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 12.4 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 07-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the veterinarian reported the following event for Hobo, a 4 year old, 12.4 pound, neutered male, Domestic Shorthair (Crossbreed).<br>7 Jun 2018: 1 vial of FRONTLINE PLUS CATS (R41005AW) was given to the cat topically between the shoulder blades, by the owner. The cat has been on the product before for an unknown amount of time. The cat became lethargic. The cat has had the same symptoms before using the product.<br>The cat was seen by the veterinarian but was not given any treatment. The symptoms are ongoing. The cat has had symptoms before with the Seresto collar where the cat was lethargic and had some bleeding in its mouth. No further medical information expected. |
| 11-Jun-2018 | UAE; 18US035470; TX; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 12.00 Year(s)<br>**Weight:** 10 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 21-May-2018* | 28-May-2018* | 1 Week(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Cinder, an approximately 12 year old, approximately 10 pound, neutered male, Feline (unknown).<br>21 May 2018*: 1 vial of FRONTLINE PLUS CATS (L40709AX) was given to the cat topically between the shoulder blades, by the owner. This was the first dose applied.<br>28 May 2018*: The cat lost fur at the application site, about the size of a silver dollar.<br>The cat was not seen by the veterinarian or given any treatment. The symptoms are still ongoing. No further medical information expected. |
| 11-Jun-2018 | UAE; 18US035490; NC; U.S.A | **Species:** Canine<br>**Breed:** Pomeranian<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 9 lbs | 4 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 04-May-2018 | 06-Jun-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Molly, 4 year old, 9 pound, spayed female, Pomeranian canine.<br>4 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R6083AL) was applied between the shoulder blades.<br>6 Jun 2018: The pet began itching and experienced irritation at the application site.<br>11 Jun 2018: The symptoms are still ongoing.<br>The dog also received the product 4 May 2018 and no symptoms occurred. There are 5 other pets in the household that also received the product. Two of the dogs also experienced those symptoms (see case 18US035518, and 18US035519). No further medical information is expected. |
| 11-Jun-2018 | UAE; 18US035518; NC; U.S.A | **Species:** Canine<br>**Breed:** Rat Terrier<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 11 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used** | 04-May-2018 | 06-Jun-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Lucky, 5 year old, 11 pound, spayed female, Rat Terrier canine.<br>4 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R6083AL) was applied between the shoulder blades.<br>6 Jun 2018: The pet began itching and experienced irritation at the application site.<br>11 Jun 2018: The symptoms are still ongoing.<br>The dog also received the product 4 May 2018 and no symptoms occurred. There are 5 other pets in the household that also received the product. Two of the dogs also experienced symptoms (see case 18US035490, and 18US035519). No further medical |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **ok?:** Yes | | | | | information is expected. |
| 11-Jun-2018 | UAE; 18US035519; NC; U.S.A | **Species:** Canine<br>**Breed:** Rat Terrier<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 11 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 04-May-2018 | 06-Jun-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Lucky, 5 year old, 11 pound, spayed female, Rat Terrier canine.<br>4 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R6083AL) was applied between the shoulder blades.<br>6 Jun 2018: The pet began itching and experienced irritation at the application site.<br>11 Jun 2018: The symptoms are still ongoing.<br>The dog also received the product 4 May 2018 and no symptoms occurred are 5 other pets in the household that also received the product. Two of the dogs also experienced those symptoms (see case 18US035490, and 18US035518). No further medical information is expected. |
| 11-Jun-2018 | UAE; 18US035537; WI; U.S.A | **Species:** Feline<br>**Breed:** Calico<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 8 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 04-Jun-2018 | 07-Jun-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Vannah, 3 year old, 8 pound, spayed female, Calico feline.<br>4 Jun 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades.<br>7 Jun 2018: The cat experienced hypersalivation and began walking in circles. The pet was not presented to the clinic and no treatment was provided.<br>11 Jun 2018: The symptoms are still ongoing.<br>No further medical information is expected. |
| 11-Jun-2018 | UAE; 18US035597; PA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 12 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 07-Jun-2018 | 07-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Momma, an approximately 10 year old, approximately 12 pound, spayed female, feline (unknown).<br>7 Jun 2018: 1 dose of FRONTLINE PLUS CATS (R41005AW) was given to the cat topically between the shoulder blades, by the owner. This was the first dose applied. The cat started vomiting and recovered the same day.<br>The cat was not seen by the veterinarian or given any treatment.<br>No further medical information expected. |
| 11-Jun-2018 | UAE; 18US035619; WI; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 11.00 Year(s)<br>**Weight:** 12 lbs | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-May-2007* | 29-May-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Rusty, 11 year old, 12 pound, neutered male, feline.<br>26 May 2018: One vial of FRONTLINE PLUS CATS (J40704AW) was applied between the shoulder blades.<br>29 May 2018: The pet experienced hair loss at the application site. The pet was not presented tot the clinic and no treatment was provided.<br>11 Jun 2018: The symptoms are still ongoing.<br>The cat has received FRONTLINE since 1 May 2007 and no symptoms presented. There are 2 other cats in the household that also received the product and are asymptomatic. No further medical information is expected. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 11-Jun-2018 | UAE; 18US035749; PA; U.S.A | **Species:** Canine **Breed:** Retriever (Golden) **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 110 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 11-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Jaxx, 110 pound, male, Golden Retriever Poodle mix canine.<br>11 Jun 2018: An unknown amount of FRONTLINE PLUS DOG 89-132 (H65903AR) was applied between the shoulder blades. The pet's skin turned a blood red at the application site. It is unknown if the pet was presented to the clinic. The owner bathed the pet which seemed to improved the redness. The current status of the pet is unknown.<br>No further medical information is expected. |
| 11-Jun-2018 | UAE; 18US035756; PA; U.S.A | **Species:** Canine **Breed:** Maltese **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 10-Jun-2018* | 10-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Shaggy, a Maltese canine (all other signalments unknown).<br>10 Jun 2018*: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (P62503AX) was applied topically at a unknown location. The pet experienced lethargy, constipation, and vomiting . It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 12-Jun-2018 | UAE; 18US035792; KY; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 04-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for a canine (all other signalments unknown).<br>4 Jun 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied topically at a unknown location.<br>Unknown date: The pet experienced intense itching which cause the skin to bleed. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>There is one other dog in the household that also received the product and is asymptomatic. No further medical information is expected. |
| 11-Jun-2018 | UAE; 18US035809; TN; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** M **Sex qualifier:** - **Age:** 1.00 Year(s) **Weight:** 4 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 09-May-2018 | 11-Jun-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Chase, 1 year old, 4.5 pound, intact male, Chihuahua canine.<br>9 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied between the shoulder blades.<br>9 Jun 2018: Another vial was applied.<br>11 Jun 2018: The pet experienced itching, and raw underarms. The pet was not presented to the clinic and no treatment was provided. Symptoms are still ongoing.<br>There is 1 other dog in the household that did not receive the product and is asymptomatic. No further medical information is expected. |

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| 11-Jun-2018 | UAE; 18US035812; CA; U.S.A | **Species:** Canine **Breed:** American Bully **Sex:** M **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 65 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jun-2015* | 09-Jun-2018 | 8 Day(s) | D-D | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Lou, 4 year old, 65 pound, neutered male, American Bulldog canine.<br>1 Jun 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was applied between the shoulder blades.<br>9 Jun 2018: The pet experienced intense itching and irritation at the application site.<br>11 Jun 2018: Symptoms are still ongoing.<br>No further medical information is expected. |
| 11-Jun-2018 | UAE; 18US035819; NY; U.S.A | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** F **Sex qualifier:** - **Age:** 7.00 Year(s) **Weight:** 6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 09-Jun-2018 | 11-Jun-2018 | 2 Day(s) | D-B | Suspected Adverse Event: On 11 Jun 2018, the owner reported the following event for Lily, 7 year old, 6 pound, Intact female, Yorkshire Terrier canine.<br>9 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60308) was applied between the shoulder blades.<br>11 Jun 2018: The pet experienced paralysis in the hind legs. The pet was not presented to the clinic and no treatment was provided. Symptoms are still ongoing.<br>There are 2 other dog that received the product and are asymptomatic. No further medical information is expected.<br>Update 14 Jun 2018: Owner called to report Lily was presented to the clinic.<br>12 Jun 2018: The pet was presented to the clinic and diagnosed with Lyme disease. The attending veterinarian prescribed an unknown treatment.<br>14 Jun 2018: Symptoms have improved but are still ongoing.<br>There is one other dog in the household that also presented symptoms (see case 18US036985). No further medical information is expected. |
| 12-Jun-2018 | UAE; 18US035823; FL; U.S.A | **Species:** Canine **Breed:** Australian Shepherd **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 10.5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Apr-2018 | 01-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 12 June 2018, the owner reported the following event for Franky, a 10 year old, 10.5 pound, neutered male Australian Shepherd.<br>1 May 2018: Fleas were noticed and one vial of FRONTLINE PLUS DOG 5-22 LBS (R60509AL) was topically applied to the dog per label. Following the treatment the dog's itching increased.<br>The dog had no issues with the previous dose of FL and there are two other dogs in the home who also had an issue. See cases 18US036215 and 18US036215. No further medical information expected. |
| 12-Jun-2018 | UAE; 18US035876; SC; U.S.A | **Species:** Canine **Breed:** Pomeranian **Sex:** F **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 9.000 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE | 05-Jun-2018 | 06-Jun-2018 | 1 Day(s) | D-C | Suspected Adverse Event: On 12 June 2018, the owner reported the following event for Bijou, a 9 pound female Pomeranian.<br>5 June 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied to the dog.<br>6 June 2018: The dog was not feeling well, dehydrated, vomiting, and had blood in its stool.<br>9 June 2018: The dog was taken to the vet.<br>No further medical information available.<br>UPDATE 13 Jun 2018: The owner reported the following for Bijou, an approximately 10 year old, 9 pound, spayed female, Pomeranian. |

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| | | | | | | CHEWABLE 68MCG/163MG; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | 2008*: The dog started on 1 dose of HEARTGARD PLUS (68 MCG/57 MG) (6BC0541, 30 Aug 2019) given orally, by the owner. 9 May 2018*: The dog was given another dose of the HEARTGARD PLUS. 5 Jun 2018: The FRONTLINE PLUS was applied topically between the shoulder blades, by the owner. This was the first application. The dog was seen by the veterinarian and given a Cerenia injection, Metronidazole, and Imodium. The dog is much better but some symptoms are still ongoing. No further medical information expected. |
| 12-Jun-2018 | UAE; 18US035994; FL; U.S.A | **Species:** Canine **Breed:** Shih Tzu **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 18 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jun-2017* | 10-Jun-2018 | 9 Day(s) | D-D | Suspected Adverse Event: On 12 June 2018, the owner reported the following event for Alphie, an 18 pound, Shih Tzu. 1 June 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) (lot and expiration unknown) was applied to the dog. 10 June 2018: The dog developed an open wound at the application site. No further medical information available. |
| 12-Jun-2018 | UAE; 18US036045; WI; U.S.A | **Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 7.5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 04-Jun-2018* | 06-Jun-2018 | 2 Day(s) | D-B | Suspected Adverse Event: On 12 Jun 2018, the manager reported the following event for Vannah, a 2 year old (born 17 Sept 2015) 7.5 pound female spayed indoor/outdoor Domestic Shorthair. 4 Jun 2018: The pet owner applied a dose of FRONTLINE PLUS CATS (P41510DW) topically down to the skin between the shoulder blades. 6 Jun 2018: The cat started drooling. 10 Jun 2018: The cat had a seizure at home that lasted less than a minute. 12 Jun 2018: The cat had four seizures and presented to the clinic. She had an unknown number of seizures since 10 Jun 2018. The clinic treated with Phenobarbital and Taurine, and recommend bathing the cat. The cat had not had another seizure at the time of the phone call. It is unknown if the cat has had FRONTLINE prior. No further medical information expected. |
| 12-Jun-2018 | UAE; 18US036067; FL; U.S.A | **Species:** Feline **Breed:** Bengal **Sex:** M **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 15.5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 08-Jun-2018 | 08-Jun-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 12 Jun 2018, the veterinarian reported the following event for Miko, a 15.5 pound, 6 year old*, neutered male Bengal. 8 Jun 2018: Miko started on the FRONTLINE PLUS CATS (Product Unsubstantiated)(Lot and Expiration Unknown). One dose was given on this date. A few hours later, the pet seemed wobbly and fatigued. Per the owner, his vocalizations seemed hoarser and overall appeared to be weaker. 12 Jun 2018: The pet was presented to the clinic. Miko is currently in clinic. The product was not washed off. Treatment has not started at this time. No further information at this time. |
| 12-Jun-2018 | UAE; 18US036180; | **Species:** Canine **Breed:** Poodle | 3 | 1 | 0 | **Product used:** FIPRONIL | 01-Apr-2015 | 12-Jun-2018 | 10 Week(s) 2 Day(s) | D-D | Suspected Adverse Event: On 13 June 2018, the owner reported the following event for Dexter, a 5 year old, 6.5 pound, intact male |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | NY; U.S.A | (Miniature)<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 5.00 Year(s)<br>**Weight:** 6.5 lbs | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** - | | | | | Poodle (miniature).<br>1 April 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (M63408AL) was applied to the dog per label.<br>12 June 2018: The dog was diagnosed with Blepharitis and prescribed an unknown medication. The dog eye is raw and irritated.<br>The dog has been on FL on and off for the past 3 years with no issues. There are two other FL treated dogs in the home who did not have an issue. No further medical information available. |
| 12-Jun-2018 | UAE; 18US036214; FL; U.S.A | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Apr-2018 | 01-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 12 June 2018, the owner reported the following event for Zapena, a 5 year old, 10 pound, spayed female Chihuahua.<br>1 May 2018: Fleas were noticed and one vial of FRONTLINE PLUS DOG 5-22 LBS (R60509AL) was topically applied to the dog per label. Following the treatment the dog's itching increased.<br>The dog had no issues with the previous dose of FL and there are two other dogs in the home who also had an issue. See cases 18US036215 and 18-35823. No further medical information expected. |
| 12-Jun-2018 | UAE; 18US036215; FL; U.S.A | **Species:** Canine<br>**Breed:** Terrier Breeds (500 Series)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 12.5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Apr-2018 | 01-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 12 June 2018, the owner reported the following event for Scrappy, a 5 year old, 12.5 pound, neutered male Terrier.<br>1 May 2018: Fleas were noticed and one vial of FRONTLINE PLUS DOG 5-22 LBS (R60509AL) was topically applied to the dog per label. Following the treatment the dog's itching increased.<br>The dog had no issues with the previous dose of FL and there are two other dogs in the home who also had an issue. See cases 18US035823 and 18US036214. No further medical information expected. |
| 12-Jun-2018 | UAE; 18US036219; -; U.S.A | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 11.00 Year(s)<br>**Weight:** 10 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jun-2015* | 11-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 12 Jun 2018, the following event was reported to Safety Call International (SCI) by the pet owner for Boots, an 11 year old, 22 pound, female Shih Tzu.<br>11 Jun 2018: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (5060428700) (invalid lot) topically, on the skin on her back.<br>12 Jun 2018: The dog was still scratching and had areas of hair loss on her ears and back.<br>It was noted that Boots had fleas on her when the product was applied. It could not be confirmed if fleas were observed on the pet or not at the time of the report, but the owner found fleas on himself.<br>No further information at this time.<br>UPDATE 13 Jun 2018: Per the owner, Boots is an 8 year old, 10-11 pound, spayed female, Shih Tzu.<br>11 Jun 2018: One vial of FRONTLINE PLUS FOR DOG 5-22 LBS (P60208AL) was applied between the shoulder blades. The pet experienced generalized hair loss on the head, ears and back.<br>12 Jun 2018: The pet was bathed with Palmolive dish detergent.<br>The dog has not been seen by the veterinarian and the symptoms |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | are ongoing. No further medical information expected. |
| 13-Jun-2018 | UAE; 18US036236; NJ; U.S.A | **Species:** Canine **Breed:** Beagle **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 15 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Unknown medications; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2007* | 08-Jan-2012* | 1 Week(s) | D-C | Suspected Adverse Event: On 13 Jun 2018, a pet owner reported the following event for Kate, an 11 year old, 15 pound, spayed female Beagle.<br>2007-2008*: The dog received unknown medications since she was ill after being rescued from a puppy mill.<br>2007-2012: The pet owner applied one full vial of FRONTLINE PLUS DOG 5-22 LBS (lot number unknown), topically, between the shoulder blades, on a monthly basis. Each time the product was applied, the dog would start to experience intermittent tremors approximately 1 week later. The tremors would last for a few seconds and would occur approximately 3 times throughout the month. The dog never presented to the veterinary clinic for examination or treatment for the symptom noted following product application.<br>2012: The pet owner discontinued product use, and the tremors stopped.<br>No further medical information expected. |
| 13-Jun-2018 | UAE; 18US036240; MI; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 9 lbs | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jun-2010* | 07-Jun-2018 | 0 Day(s) | D-A | Suspected Adverse Event: On 13 Jun 2018, the veterinarian reported the following event for Smokey, a 9 pound, 10 year old*, neutered male Domestic Shorthair.<br>1 Jun 2010*: Smokey started on the FRONTLINE PLUS CATS (R40101AW).<br>7 Jun 2018: The most recent dose was applied in an unknown location. About 3 hours later, the pet seemed disoriented and wobbly in his hind legs.<br>8 Jun 2018: The symptoms were ongoing so the owner attempted to wash the product off with an unknown shampoo. The owner also noticed that the pet's eyes were red.<br>9 Jun 2018: Smokey presented to the clinic and was still ataxic in his hind legs. The vet stated that he had bilateral retinal detachment and mild congestion of conjunctiva in both eyes. A negative FIV test was performed via an unknown test. A complete CBC and blood chemistry was performed with results WNL. A toxoplasmosis test was performed via Antech, but results are unknown at this time. The pet was treated with clindamycin and Neo-Poly-Dex eye drops.<br>10 Jun 2018*: The pet remained in clinic. The vet noticed that the bladder was turgid. Urination was expressed via vet manually.<br>11 Jun 2018: Radiographs were performed which were deemed unremarkable. He was given I/V fluids.<br>13 Jun 2018: The pet experienced a seizure.<br>The pet is still in clinic with ongoing symptoms. The pet has received the product seasonally since Jun 2010* without any adverse effect. No further information at this time.<br>UPDATE 13 Jun 2018: Per the veterinarian, the pet was euthanized. A necropsy is planned. No further information at this time.<br>UPDATE 12 Jul 2018: Per medical record, the pet tested pos via IGG titer for toxoplasmosis. Necropsy results revealed lymphoma affecting the eye, heart and lungs, which could have caused an embolic event resulting in the other clinical signs and the pet's quick demise. There was no connection between the FRONTLINE PLUS CATS and the pet's condition. No further medical information expected. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 13-Jun-2018 | UAE; 18US036345; -; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Species not indicated / recommended) | 11-Jun-2018 | 11-Jun-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 13 Jun 2018, a clinic staff reported the following event to Safety Call International (anti-poison center) for Gracie, a 2 year old, spayed female, Feline.<br>11 Jun 2018: The cat was accidentally dosed with FRONTLINE PLUS DOG 45-88 LBS (lot number unknown). The cat has some mild twitching occasionally, however her vitals are normal and exam was normal.<br>No further medical information expected. |
| 13-Jun-2018 | UAE; 18US036370; CO; U.S.A | **Species:** Canine **Breed:** Poodle (Miniature) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 16 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2017* | 12-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 13 Jun 2018, the owner reported the following event for Oscar, an approximately 1 year old, 16 pound, neutered male, Poodle (Miniture).<br>2017*: The dog started on 1 dose of FRONTLINE PLUS DOG 5-22 LBS (P61522AL) given to the dog topically between the shoulder blades, by the owner. The dog was treated monthly but was not treated during the winter.<br>12 Jun 2018: The dog received another dose of the product. The same day, the dog was very itchy around the top half of his body . The dog was not seen by a veterinarian or given any treatment. The symptoms are better but still ongoing. No further medical information expected. |
| 13-Jun-2018 | UAE; 18US036378; CA; U.S.A | **Species:** Canine **Breed:** Shetland Sheep Dog (Sheltie) **Sex:** F **Sex qualifier:** Neutered **Age:** 12.00 Year(s) **Weight:** 24 lbs | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 01-Aug-2017* | 0 Day(s) | D-A | Suspected Adverse Event: On 13 Jun 2018, the owner reported the following event for Emmy, 12 year old, 24 pound, spayed female, Shetland Sheep Dog canine.<br>1 Aug 2017*: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was applied between the shoulder blades. After a few hours the pet experienced intense itching. The pet was not presented to the clinic. The owner bathed the pet and applied an anti itch ointment.<br>Sept 2017*: The pet passed away.<br>The dog has received the product on prior unknown date and no symptoms presented. There is one other dog in the household that did not receive the product and was asymptomatic. No further medical information is expected. |
| 13-Jun-2018 | UAE; 18US036426; TX; U.S.A | **Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Month(s) **Weight:** 6 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 08-Jun-2018* | 09-Jun-2018* | 1 Day(s) | D-C | Suspected Adverse Event: On 13 Jun 2018, the owner reported the following event for a spayed female, Domestic Medium Hair (Crossbreed) (all other signalments unknown).<br>Unknown Date: A few drops of FRONTLINE PLUS CATS (M40205AW) was given to the cat topically (unknown site of application), by the owner. It is unknown if this was the first application. An unknown amount of time after the application the cat was ataxic, not eating, dehydrated and had runny stool.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected.<br>UPDATE 14 Jun 2018: The owner reported the following for Bella, an approximately 3 month old, 6 pound, feline. |

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| | | | | | | | | | | | 8 Jun 2018*: The cat was given the product between the shoulder blades. This was the first application.<br>9 Jun 2018*: The symptoms started.<br>The cat was seen by the veterinarian and given IV fluids and Metronidazole. The cat is improving but the symptoms are still ongoing. No further medical information expected. |
| 13-Jun-2018 | UAE; 18US036446; GA; U.S.A | **Species:** Canine<br>**Breed:** Pit Bull<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 7.00 Month(s)<br>**Weight:** 25 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** PO-Oral<br>**Was the product used ok?:** No (Route not indicated / recommended) | 13-Jun-2018 | 13-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 13 Jun 2018, the owner reported the following event for Junior, an approximately 7 month old, approximately 25 pound, intact male, Pit Bull.<br>13 Jun 2018: 2 vials of FRONTLINE PLUS DOG (lot unknown, product unsubstantiated) was given to the dog orally. The dog started running around and licking his lips.<br>The dog was not seen by a veterinarian or given any treatment. It is unknown if the symptoms are ongoing. No further medical information expected. |
| 13-Jun-2018 | UAE; 18US036480; FL; U.S.A | **Species:** Canine<br>**Breed:** Fox Terrier<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 18.00 Year(s)<br>**Weight:** 11 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Phenobarbital; Dasuquin; Diethylstilbestrol;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 15-May-2018 | 16-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 13 Jun 2018, the owner reported the following event for Shiloh, an approximately 18 year old, approximately 11 pound, spayed female, Fox Terrier.<br>2003*: The dog started on Phenobarbital.<br>2012*: The dog started on Dasuquin.<br>2013*: The dog started on Diethylstilbestrol.<br>20 Apr 2018: The dog received Diethylstilbestrol.<br>15 May 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was given to the dog topically between the shoulder blades, by the owner. This was the first dose applied. The dog also received Phenobarbital and Dasuquin.<br>16 May 2018: The dog vomited once.<br>The dog was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 13-Jun-2018 | UAE; 18US036542; KY; U.S.A | **Species:** Canine<br>**Breed:** Pit Bull<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 14.00 Year(s)<br>**Weight:** 55 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 09-Jun-2018 | 11-Jun-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 13 Jun 2018, the owner reported the following event for Voodoo, 14 year old, 55 pound, spayed female, Pit Bull canine.<br>9 Jun 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (P61601AR) was applied between the shoulder blades.<br>11 Jun 2018: The pet experienced a scab at the application site. The pet was not presented to the clinic and no treatment was provided.<br>13 Jun 2018: Symptoms are still ongoing.<br>There are 2 other dogs in the household that also received the product and are asymptomatic. No further medical information is expected. |
| 13-Jun-2018 | UAE; 18US036576; CA; U.S.A | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other | 12-Jun-2018 | 13-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 13 Jun 2018, the owner reported the following event for Molly, 7 year old, 100 pound, spayed female, Labrador Retriever canine.<br>12 Jun 2018: One vial of FRONTLINE PLUS DOG 89-132 LBS (P60712) was applied between the shoulder blades.<br>13 Jun 2018: The pet experienced hives all over the body. The pet was not presented to the clinic and no treatment was provided. |

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| | | **Weight:** 100 lbs | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | Symptoms are still ongoing.<br>No further medical information is expected. |
| 14-Jun-2018 | UAE; 18US036657; OK; U.S.A | **Species:** Canine<br>**Breed:** Pinscher (Miniature)<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 9.00 Year(s)<br>**Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 28-Mar-2018* | 28-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 14 Jun 2018, the owner reported the following event for a Pinscher (Miniature) (all other signalments unknown).<br>28 May 2018*: An unknown amount of FRONTLINE PLUS DOG 23-44 LBS (R60516BL) was given to the dog topically (unknown site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application the dog was itching more and losing hair. The dog had fleas prior to the first application and is still seeing fleas.<br>The dog was seen by a veterinarian and given a Prednisone injection. The dog's current status is unknown. There was another dog treated with the product that had the same problems (see case 18US036807). No further medical information expected.<br>UPDATE 14 Jun 2018: The owner reported the following for Lily, a 9 year old, 10 pound, non-pregnant non-lactating intact female.<br>Mar 2018*: The dog started on the product. The owner splits the product between multiple dogs.<br>28 May 2018*: The dog was given a split vial of the product. The symptoms started the same day.<br>The dog was seen by the veterinarian and given and unknown injection. The symptoms are ongoing. No further medical information expected. |
| 14-Jun-2018 | UAE; 18US036678; IA; U.S.A | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 11.00 Year(s)<br>**Weight:** 6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jun-2007* | 01-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 14 Jun 2018, the owner reported the following event for Teddy, 11 year old, 6 pound, spayed female, Yorkshire Terrier canine.<br>1 Jun 2018: One vial of FRONTLINE PLUS DOG 5- 22 LBS (R60525AL) was applied between the shoulder blades.<br>Unknown date: The pet experienced increased itching. The pet was not presented to the clinic and no treatment was provided.<br>14 Jun 2018: The symptoms are still ongoing.<br>The pet has received the product since 1 Jun 2007 and no symptoms presented. There is one other dog in the household that also received the product and experienced symptoms (see case 18US036690). No further medical information is expected. |
| 14-Jun-2018 | UAE; 18US036690; IA; U.S.A | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 15 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jun-2007* | 01-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 14 Jun 2018, the owner reported the following event for Masi, 6 year old, 15 pound, spayed female, Yorkshire Terrier canine.<br>1 Jun 2018: One vial of FRONTLINE PLUS DOG 5- 22 LBS (R60525AL) was applied between the shoulder blades.<br>Unknown date: The pet experienced increased itching. The pet was not presented to the clinic and no treatment was provided.<br>14 Jun 2018: The symptoms are still ongoing.<br>The pet has received the product since 1 Jun 2007 and no symptoms presented. There is one other dog in the household that also received the product and experienced symptoms (see case 18US036678). No further medical information is expected. |

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| 14-Jun-2018 | UAE; 18US036754; NC; U.S.A | **Species:** Canine **Breed:** Boxer **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 50 lbs | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-May-2010 | 14-Jun-2018 | 13 Day(s) | D-D | Suspected Adverse Event: On 14 June 2018, the owner reported the following event for Zoe, a 8 year old, 50 pound, spayed female Boxer/Beagle mix.<br>1 June 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (FL) (lot unknown) was applied to the dog per label.<br>14 June 2018: The dog had hair loss and skin irritation at the application site.<br>The dog has been on FL for year with no issues. No further medical information available. |
| 14-Jun-2018 | UAE; 18US036776; GA; U.S.A | **Species:** Feline **Breed:** Persian, Tortoiseshell **Sex:** F **Sex qualifier:** Neutered **Age:** 9.00 Year(s) **Weight:** 7 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 20-Mar-2018 | 09-Apr-2018* | N/A | D-D | Suspected Adverse Event: On 14 June 2018, the owner reported the following event for Holly, a 9 year old, 7 pound, spayed female Tortoiseshell cat.<br>*20 March 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied per label the cat for the first time.<br>*9 April 2018: The cat was itching prior to the treatment, but the itching increased around this time and the cat did not have fleas. The cat continued to itch and scratch until the last dose given in May 2018 and the symptoms are still ongoing. The cat has not been seen by the vet. No further medical information available. |
| 14-Jun-2018 | UAE; 18US036807; OK; U.S.A | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 10.00 Year(s) **Weight:** 16 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Off label use / Indication) | 28-May-2015* | 28-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 14 Jun 2018, the owner reported the following event for a Yorkshire Terrier (all other signalments unknown).<br>28 May 2018*: An unknown amount of FRONTLINE PLUS DOG 23-44 LBS (R60516BL) was given to the dog topically (unknown site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application the dog was itching more and losing hair. The dog had fleas prior to the first application and is still seeing fleas.<br>The dog was seen by a veterinarian and given a Prednisone injection. The dog's current status is unknown. There was another dog treated with the product that had the same problems (see case 18US036657). No further medical information expected.<br>UPDATE 14 Jun 2018: The owner reported the following for Ricky, a 10 year old, 16 pound, neutered male.<br>2015*: The dog started on the product. The owner splits the product between multiple dogs.<br>28 May 2018*: The dog was given a split vial of the product. The symptoms started the same day.<br>The dog was seen by the veterinarian and given and unknown injection. The symptoms are ongoing. No further medical information expected. |
| 14-Jun-2018 | UAE; 18US036887; FL; U.S.A | **Species:** Canine **Breed:** Dachshund **Sex:** F **Sex qualifier:** - **Age:** 6.00 Year(s) **Weight:** 19 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other | 02-Jun-2018 | 04-Jun-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 14 Jun 2018, the owner reported the following event for Nadia, 6 year old, 19 pound, Intact female, Dachshund canine.<br>2 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied between the shoulder blades.<br>4 Jun 2018: The pet experienced intense itching and bald spots throughout the body. The pet was not presented to the clinic and no treatment was provided. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | 15 Jun 2018: The symptoms are still ongoing.<br>There is one other dog in the household that also received the product and experienced symptoms (see case 18US037088). No further medical information is expected. |
| 14-Jun-2018 | UAE; 18US036975; NY; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Golden)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Month(s)<br>**Weight:** 51 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 31-May-2018 | 05-Jun-2018 | 5 Day(s) | D-D | Suspected Adverse Event: On 14 Jun 2018, the owner reported the following event for Max, 8 month old, 51 pound, neutered male, Golden Retriever canine.<br>31 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>5 Jun 2018: The pet experienced bumps and scab mainly at the application site and on the stomach.<br>Unknown date: The pet also had diarrhea and a ear infection.<br>14 Jun 2018: The pet was presented to the clinic. The attending veterinarian only treated for diarrhea and ear infection. Symptoms are improving but still ongoing.<br>No further medical information is expected. |
| 14-Jun-2018 | UAE; 18US036976; MN; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 14-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 14 Jun 2018, the owner reported the following event for a spayed female, Domestic Shorthair feline (all other signalment unknown).<br>Unknown date: An unknown amount of FRONTLINE PLUS CATS (lot unknown) was applied at an unknown location topically. The pet experienced hair loss and skin irritation. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 14-Jun-2018 | UAE; 18US036979; NJ; U.S.A | **Species:** Canine<br>**Breed:** Boxer<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 12.00 Year(s)<br>**Weight:** 80 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 08-Jun-2018 | 1 Week(s) | D-D | Suspected Adverse Event: On 14 Jun 2018, the owner reported the following event for Joe, 12 year old, 80 pound, neutered male, Boxer canine.<br>1 Jun 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was applied between the shoulder blades.<br>8 Jun 2018: The pet experienced intense itching.<br>14 Jun 2018: The pet was presented to the clinic. The attending veterinarian prescribed an unknown anti itch medication.<br>15 Jun 2018: Symptoms are still ongoing.<br>The dog received the FRONTLINE on prior unknown date and no symptoms presented. No further medical information is expected. |
| 14-Jun-2018 | UAE; 18US036985; NY; U.S.A | **Species:** Canine<br>**Breed:** Terrier Breeds (500 Series)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 55 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / | 10-Jun-2018 | 14-Jun-2018 | 4 Day(s) | D-B | Suspected Adverse Event: On 14 Jun 2018, the owner reported the following event for Rufus, 8 year old, 55 pound, neutered male, Terrier canine.<br>10 Jun 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201) was applied between the shoulder blades.<br>14 Jun 2018: The pet experienced paralysis in the front left and back left legs. The pet was not presented to the clinic and no treatment was provided. Symptoms are still ongoing.<br>There is one other dog in the household that also received the |

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| | | | | | | Cutaneous<br>**Was the product used ok?:** Yes | | | | | FRONTLINE and experienced symptoms (see case 18US35819).<br>No further medical information is expected. |
| 15-Jun-2018 | UAE; 18US037088; FL; U.S.A | **Species:** Canine<br>**Breed:** Dachshund<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 2.00 Year(s)<br>**Weight:** 18 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 02-Jun-2018 | 04-Jun-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 14 Jun 2018, the owner reported the following event for Rickey, 2 year old, 18 pound, Intact male, Dachshund canine.<br>2 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied between the shoulder blades.<br>4 Jun 2018: The pet experienced intense itching. The pet was not presented to the clinic and no treatment was provided.<br>15 Jun 2018: The symptoms are still ongoing.<br>There is one other dog in the household that also received the product and experienced symptoms (see case 18US036887). No further medical information is expected. |
| 15-Jun-2018 | UAE; 18US037198; OH; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 15-Jun-2018* | 0 Day(s) | D-C | Suspected Adverse Event: On 15 Jun 2018, the owner reported the following event for a canine (all other signalments unknown).<br>Unknown date: An unknown amount of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown) was applied topically. The pet experienced an off balance walk. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 15-Jun-2018 | UAE; 18US037217; OH; U.S.A | **Species:** Canine<br>**Breed:** Retriever (Labrador, Chocolate)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Month(s)<br>**Weight:** 65 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 272MCG/652MG ;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 10-Oct-2015 | 25-Nov-2015 | N/A | D-C | Suspected Adverse Event: On 15 Jun 2018 the pet owner reported the following event for Hely, a 2 year old (born 27 Jul 2015), 65 pound, spayed female Chocolate Labrador Retriever.<br>10 Oct 2015: Started on HEARTGARD PLUS (272 MCG/227 MG) (lot and expiration unknown) and FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown) once monthly.<br>25 Nov 2015: The dog began scratching at the eyes and developed alopecia at that site.<br>4 Dec 2015: The dog presented to the clinic and was treated with prednisone and Apoquel.<br>1 Jul 2017: The pet owner discontinued both products.<br>*23 Jul 2017: The dog recovered.<br>No further medical information is expected. |
| 15-Jun-2018 | UAE; 18US037254; CA; U.S.A | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 3.00 Month(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products** | 11-Jun-2018 | 12-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 15 June 2018, the owner reported the following event for Stash, a 3 month old, 7 pound, intact male Chihuahua.<br>11 June 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown) was applied per label to the dog for the first time, the dog licked the application. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 7 lbs | | | | **used:** no other products<br>**Route:** -<br>**Was the product used ok?:** Yes | | | | | 12 June 2018: The dog started to not eat, looks sad, and he started to vomit.<br>The dog also didn't have a bowel movement for a few days. The dog symptoms are improving but still ongoing, the owner is monitoring the dog. No further medical information available. |
| 15-Jun-2018 | UAE; 18US037263; CA; U.S.A | **Species:** Canine<br>**Breed:** Boxer<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 15-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 15 Jun 2018, the owner reported the following event for Bailey, Boxer canine (all other signalments unknown).<br>Unknown date: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (P60104AR) was applied topically. The pet experienced a rash on the stomach and legs. The owner bathed the pet and the pet recovered. After 2 days the rash reappeared. It is unknown if the pet was presented to the clinic. The current status of the pet is unknown.<br>No further medical information is expected. |
| 15-Jun-2018 | UAE; 18US037290; FL; U.S.A | **Species:** Canine<br>**Breed:** Australian Cattle Dog<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 55 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 28-May-2018 | 28-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 18 June 2018, the pet owner's roommate reported the following event for Bran, a 55 pound Australian Cattle Dog.<br>28 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61513AR) was applied to the dog. The dog was itching and had fleas before the treatment. Following the treatment the dog itching increased.<br>No further medical information available. |
| 15-Jun-2018 | UAE; 18US037323; CA; U.S.A | **Species:** Canine<br>**Breed:** Mastiff<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 3.00 Year(s)<br>**Weight:** 115 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 13-Jun-2018 | 14-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 15 Jun 2018, the owner reported the following event for Jules, 3 year old, 115 pound, intact male, Mastiff canine.<br>13 Jun 2018: One vial of FRONTLINE PLUS DOG 89-132 (P62606AR) was applied between the shoulder blades.<br>14 Jun 2018: The pet experienced hair loss and irritation at the application site.<br>15 Jun 2018: The irritation worsened and started to bleed. The pet has not been presented to the clinic and no treatment was provided. Symptoms are still ongoing.<br>There is one other dog in the household that did not receive the product and is asymptomatic. No further medical information is expected. |
| 15-Jun-2018 | UAE; 18US037333; KY; U.S.A | **Species:** Canine<br>**Breed:** Terrier (Jack Russell)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 18.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products | N/A | 14-Jun-2018 | 0 Day(s) | D-B | Suspected Adverse Event: On 15 Jun 2018, the owner reported the following event for Reenie, 18 year old, 16 pound, spayed female, Jack Russell Terrier canine.<br>14 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P62719BL) was applied between the shoulder blades. The pet experienced diarrhea, vomiting, and a seizure lasting a few seconds. The pet was not presented to the clinic and no treatment was provided. |

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| | | **Weight:** 16 lbs | | | | **Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | 15 Jun 2018: The symptoms are still ongoing.<br>There is one other dog in the household that did not receive the product and is asymptomatic. No further medical information is expected. |
| 18-Jun-2018 | UAE; 18US037366; PA; U.S.A | **Species:** Canine<br>**Breed:** Beagle<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 01-Jan-2018* | 07-Jan-2018* | 6 Day(s) | D-B | Suspected Adverse Event: On 18 Jun 2018, the owner reported the following event for a neutered male Beagle (all other signalments unknown).<br>Unknown Date: An unknown amount of FRONTLINE (lot unknown, product unsubstantiated) was given to the dog (unknown route and site of application), by the owner. It is unknown if this was the first application. Approximately 1 week later, the dog had a seizure.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected. |
| 18-Jun-2018 | UAE; 18US037374; NJ; U.S.A | **Species:** Canine<br>**Breed:** Cockapoo<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 22 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG;<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 14-Jun-2011* | 15-Jun-2018 | 2 Week(s) | D-D | Suspected Adverse Event: On 18 Jun 2018, a pet owner reported the following event for Dusty, an approximately 7 year old, 22 pound, male neutered Cockapoo mix.<br>2011: The dog started HEARTGARD PLUS (68 MCG/57 MG)(lot and expiration date unknown).<br>14 Jun 2018: The last chew was given.<br>15 Jun 2018: The owner found vomit in the house and stated part of the HEARTGARD PLUS chew was in the vomit. The dog recovered.<br>The dog is also on FRONTLINE PLUS DOG 5-22 LBS and the last dose was applied on an unknown date. No further medical information expected. |
| 18-Jun-2018 | UAE; 18US037387; CA; U.S.A | **Species:** Canine<br>**Breed:** Fox Terrier (Wire-Haired)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Month(s)<br>**Weight:** 12 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-May-2018* | 26-May-2018* | N/A | D-D | Suspected Adverse Event: On 18 Jun 2018, the owner reported the following event for a male, Fox Terrier (Wire-Haired) (all other signalments unknown).<br>Unknown Date: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (P61522AL) was given to the dog (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the dog was scratching and biting.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected.<br>UPDATE 22 Jun 2018: The owner reported the following for Axel, a 6 month old, approximately 12 pound, neutered male.<br>1 May 2018*: The dog started on 1 vial of FRONTLINE PLUS DOG 5-22 LBS (P61522AL) given to the dog topically between the shoulder blades, by the owner. This was the first dose applied. The dog had fleas prior to the first dose.<br>26 May 2018*: The owner noticed the dog scratching and biting. The symptoms were continuous.<br>28 May 2018*: The dog was given another dose of the product. The dog was seen by a veterinarian and given Prednisone. The |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | symptoms are improving but still ongoing. No further medical information expected. |
| 18-Jun-2018 | UAE; 18US037420; FL; U.S.A | **Species:** Canine **Breed:** Maltese **Sex:** F **Sex qualifier:** Unknown **Age:** 11.00 Year(s) **Weight:** 10 lbs | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 10-Jun-2018* | 14-Jun-2018 | 4 Day(s) | D-A | Suspected Adverse Event: On 18 Jun 2018, a family member reported the following event for Molly, an approximately 11 year old, approximately 10 pound, female, Maltese (all other signalments unknown).<br>10 Jun 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was given to the dog topically, between the shoulder blades, by the family member. It is unknown if this was the first dose received.<br>14 Jun 2018: The dog died on its own.<br>The dog was not seen by a veterinarian or given any treatment. Prior to the application, the dog was missing hair and was thin from weight loss (unknown cause). No further medical information expected. |
| 18-Jun-2018 | UAE; 18US037490; IA; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 25-May-2018 | 25-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 18 Jun 2018, the owner reported the following event for an unknown canine (all signalments unknown).<br>25 May 2018: 1 dose of FRONTLINE PLUS DOG (lot unknown, product unsubstantiated) was given to the dog topically (unknown site of application, by the owner. This was the first dose applied.<br>On an unknown date after the application, the dog was scratching around the ears, chin, front legs/belly, back legs, and tail. The owner has not noticed any fleas but has not really looked for them. It is unknown if the dog was seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected. |
| 18-Jun-2018 | UAE; 18US037557; MI; U.S.A | **Species:** Canine **Breed:** Norwich Terrier **Sex:** M **Sex qualifier:** Neutered **Age:** 3.50 Year(s) **Weight:** 13 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2015* | 16-Jun-2018 | 1 Day(s) | D-C | Suspected Adverse Event: On 18 Jun 2018, the owner reported the following event for Cooper, a 3.5 year old, 13 pound, neutered male, Norwich Terrier.<br>2015*: The dog started on 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60525AL) given topically, between the shoulder blades, by the owner. The dog was treated every 45 days seasonally from Apr-Oct. The dog also started on 1 dose of HEARTGARD PLUS (68 MCG/57 MG) (7BC0191, 28 Feb 2020) given orally. The dog was treated every 30 days from Mar-Nov.<br>1 May 2018: The dog received another dose of FRONTLINE PLUS DOG 5-22 LBS (R60525AL) and HEARTGARD PLUS (68 MCG/57 MG). Approximately 24-48 hours later the dog was breathing rapidly and could not stand or walk. The dog recovered after about 5 minutes.<br>1 Jun 2018: The dog received another dose of HEARTGARD PLUS (68 MCG/57 MG)<br>15 Jun 2018: The dog received another dose of FRONTLINE PLUS DOG 5-22 LBS (R60525AL).<br>16 Jun 2018: The dog had the same symptoms and recovered after about 5 minutes.<br>The dog was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 18-Jun-2018 | UAE; 18US037646; SC; U.S.A | **Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | N/A | 17-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 18 Jun 2018, the owner reported the following event for Lyndin, 7 year old, 7.5 pound, spayed female, Domestic Mediumhair feline.<br>17 Jun 2018: One vial of FRONTLINE PLUS CATS (P40414AW) |

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| | | **Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 7.5 lbs | | | | 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | was applied between the shoulder blades. The pet experienced head twitching and vomiting. The pet was not presented to the clinic and no treatment was provided.<br>18 Jun 2018: The symptoms are still ongoing.<br>There is one other cat in the household that also received the product and is asymptomatic. No further medical information is expected.<br>UPDATE 28 Jun 2018: As reported by the owner. The cat also now has hair loss at the application site, and the skin is red. The cat is still twitching if touched on the spine. The cat is also scratching at the application site. The owner has been washing the cat with Dawn. |
| 18-Jun-2018 | UAE; 18US037694; CA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 7 lbs | 4 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 06-Jun-2018* | 18-Jun-2018* | 12 Day(s) | D-D | Suspected Adverse Event: On 18 June 2018, the owner reported the following event for Mama Z, a 3 year old, 7 pound, spayed female.<br>6 June 2018: The cat was scratching and had fleas so one vial of FRONTLINE PLUS CATS (P41102AX) was applied to the cat per label for the first time, within a few hours the itching subsided.<br>18 June 2018: The cat had fleas and started back itching and scratching excessively.<br>There are 3 other treated cats in the home who is having the same issues. See cases 18US037721,18US037719, and 18US037717.<br>No further medical information available. |
| 18-Jun-2018 | UAE; 18US037717; CA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 1.00 Year(s)<br>**Weight:** 10 lbs | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 06-Jun-2018* | 18-Jun-2018* | 12 Day(s) | D-D | Suspected Adverse Event: On 18 June 2018, the owner reported the following event for Gretta, a 1 year old, 10 pound, spayed female.<br>6 June 2018: The cat was scratching and had fleas so one vial of FRONTLINE PLUS CATS (P41102AX) was applied to the cat per label for the first time, within a few hours the itching subsided.<br>18 June 2018: The cat had fleas and started back itching and scratching excessively.<br>There are 3 other treated cats in the home who is having the same issues. See cases 18US037721, 18US037721, and 18US037694.<br>No further medical information available. |
| 18-Jun-2018 | UAE; 18US037719; CA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 2.00 Year(s)<br>**Weight:** 12 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 06-Jun-2018* | 18-Jun-2018* | 12 Day(s) | D-D | Suspected Adverse Event: On 18 June 2018, the owner reported the following event for Karly Quinn, a 2 year old, 12 pound, spayed female.<br>6 June 2018: The cat was scratching and had fleas so one vial of FRONTLINE PLUS CATS (P41102AX) was applied to the cat per label for the first time, within a few hours the itching subsided.<br>18 June 2018: The cat had fleas and started back itching and scratching excessively.<br>There are 3 other treated cats in the home who is having the same issues. See cases 18US037721, 18US037717, 18US037694. No further medical information available. |
| 18-Jun-2018 | UAE; 18US037721; CA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | 06-Jun-2018* | 18-Jun-2018* | 12 Day(s) | D-D | Suspected Adverse Event: On 18 June 2018, the owner reported the following event for Cullen a neutered male.<br>6 June 2018: The cat was scratching and had fleas so one vial of FRONTLINE PLUS CATS (P41102AX) was applied to the cat per |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** Unknown | | | | 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | label for the first time, within a few hours the itching subsided.<br>18 June 2018: The cat had fleas and started back itching and scratching excessively.<br>There are 3 other treated cats in the home who is having the same issues. See cases 18US037721, 18US037719, and 18US037717.<br>No further medical information available. |
| 18-Jun-2018 | UAE; 18US037769; CA; U.S.A | **Species:** Canine<br>**Breed:** Pit Bull<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 80 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 01-Jan-2012* | 18-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 18 Jun 2018, the owner reported the following event for Charlie, a 8 year old, approximately 80 pound, neutered male, Pit Bull.<br>2012*: The dog started on 1 vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was given to the dog topically from the shoulder blades to the tail, by the owner. The dog was not treated regularly.<br>17 Jun 2018: The dog received 2 doses of the product.<br>18 Jun 2018: The dog was lethargic. The dog recovered the same day.<br>The dog was not seen by a veterinarian or given any treatment.<br>The dog has had symptoms before using the product (see case 18US038038). The dog has a prior history of bumpy/flaky skin due to what the veterinarian thinks is allergies. No further medical information expected. |
| 19-Jun-2018 | UAE; 18US038034; TX; U.S.A | **Species:** Canine<br>**Breed:** Bulldog<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 55.000 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 05-Jun-2018 | 05-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 19 Jun 2018, the owner reported the following event for a English Bulldog canine (all other signalments unknown).<br>5 Jun 2018: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was applied between the shoulder blades.<br>Unknown date: The pet experienced increased shedding. The majoriy of hair loss is on the application site. It is unknown if the pet was presented to the clinic or if any treatment was provided.<br>The status of the pet is unknwon.<br>No further medical information is expected. |
| 19-Jun-2018 | UAE; 18US038038; CA; U.S.A | **Species:** Canine<br>**Breed:** Pit Bull<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 2.00 Year(s)<br>**Weight:** 80 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not | 01-Jan-2012* | 02-Jan-2012* | 1 Day(s) | D-D | Suspected Adverse Event: On 18 Jun 2018, the owner reported the following event for Charlie, a 2 year old, approximately 80 pound, neutered male, Pit Bull.<br>2012*: The dog started on 1 vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was given to the dog topically from the shoulder blades to the tail, by the owner. The dog was not treated regularly.<br>Approximately a day after either the first or second dose of the product the dog vomited. It is not sure after which dose the symptoms happened but the symptoms only occurred after one of the applications. The dog recovered the same day.<br>The dog was not seen by a veterinarian or given any treatment.<br>The dog has a prior history of bumpy/flaky skin due to what the veterinarian thinks is allergies. No further medical information expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | respected) | | | | | |
| 19-Jun-2018 | UAE; 18US038116; OH; U.S.A | **Species:** Canine **Breed:** Boxer **Sex:** M **Sex qualifier:** - **Age:** 8.50 Year(s) **Weight:** 104 lbs | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Hartz shampoo; unknown antibiotics; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jan-2010* | 30-May-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 19 Jun 2018, the owner reported the following event for Max, an 8.5 year old, 104 pound, intact male, Boxer/Pit Bull mixed breed.<br>2010*: The dog started on 1 vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) was given to the dog topically between the shoulder blades, by the owner. The dog was treated on a year round basis every month.<br>2017*: The dog started on Hartz shampoo. The dog was bathed about every 3 weeks.<br>24 Apr 2018*: The dog had its tail docked due to a cyst. The dog started on unknown antibiotics.<br>14 May 2018*: The dog received the last of the antibiotics.<br>26 May 2018: The dog was given a bath with Hartz shampoo.<br>29 May 2018: The dog received another dose of FRONTLINE PLUS DOG 89-132 LBS.<br>30 May 2018: The owner noticed swelling or welts on the dog's hind quarts.<br>2 Jun 2018*: The dog recovered.<br>The dog was not seen by a veterinarian. The owner treated the dog with Benadryl and apple cider vinegar. No further medical information expected. |
| 19-Jun-2018 | UAE; 18US038138; OH; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 6 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 19-Jun-2018 | 19-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 19 June 2018, the owner reported the following event for KiKi, a 6 year old, 6 pound, spayed female Domestic Shorthair.<br>19 June 2018: One vial of FRONTLINE PLUS CATS (R41105AW) was applied per label to the cat. The cat turned around and licked it and started to salivate.<br>The owner is monitoring the cat's condition. There is one other treated cat in the home who did not have any issues. No further medical information available. |
| 19-Jun-2018 | UAE; 18US038194; CT; U.S.A | **Species:** Canine **Breed:** Dachshund (Miniature) **Sex:** M **Sex qualifier:** Neutered **Age:** 5.00 Year(s) **Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 27-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 19 Jun 2018, the owner reported the following event for Noodle, 10 pound, Dachshund canine (all other signalments unknown).<br>27 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied between the shoulder blades.<br>Unknown date: The pet experienced increased itching and hair loss at the application site.<br>There is one other dog in the household that also received product and is asymptomatic. No further medical information is expected.<br>UPDATE 9 Jul 2018: The owner called to report the following event for a 5 year old, neutered male.<br>28 May 2018: The pet experienced symptoms. The pet was not presented to the clinic and no treatment was provided.<br>9 Jul 2018: Symptoms are still ongoing.<br>The pet has received the product on prior unknown date and no symptoms presented. The second dog in the household also experienced symptoms (see case 18US043037). No further medical information is expected. |
| 20-Jun-2018 | UAE; 18US038231; | **Species:** Canine **Breed:** Mixed | 1 | 1 | 0 | **Product used:** FIPRONIL | 29-May-2016* | 05-Jun-2018 | 1 Week(s) | D-D | Suspected Adverse Event: On 20 Jun 2018, the owner reported the following event for Gracie, 7 year old, 30 pound, spayed |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | NC; U.S.A | Breeds / various<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 30 lbs | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | female, Mixed Breed canine.<br>29 May 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (P61014AL) was applied between the shoulder blades.<br>5 Jun 2018: The pet experienced intense itching all over the body.<br>16 Jun 2018: The pet was presented to the clinic. The attending veterinarian prescribed Prednisone.<br>20 Jun 2018: The pet recovered.<br>The pet has received the product sporadically since 29 May 2016 and the same symptoms presented. The symptoms would typically last 1 week. No further medical information is expected. |
| 20-Jun-2018 | UAE; 18US038278; FL; U.S.A | **Species:** Canine<br>**Breed:** Mixed Breeds / various<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 15.00 Year(s)<br>**Weight:** 15 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 30-May-2008* | 18-Jun-2018* | 19 Day(s) | D-D | Suspected Adverse Event: On 20 June 2018, the owner reported the following event for Pedro, a 15 year old 15 pound, neutered male mix breed Terrier.<br>30 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60509AL) was topically applied per label to the dog.<br>*18 June 2018; The dog started to itch under his belly and bottom area, it is unknown if the dog has fleas but the owner is not seeing them with the naked eye.<br>The dog has not been seen by the vet for his ongoing symptoms.<br>The dog has been on FL at least for the past 10 years with no issues. There is one other treated dog in the home who did not have any issues. No further information available. |
| 20-Jun-2018 | UAE; 18US038338; ME; U.S.A | **Species:** Canine<br>**Breed:** Hound Breeds (200 Series)<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 7.00 Year(s)<br>**Weight:** 50 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jun-2018 | 14-Jun-2018* | 13 Day(s) | D-D | Suspected Adverse Event: On 20 June 2018, the owner reported the following event for Panda, a 7 year old, 50 pound, intact female Hound.<br>1 June 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS was applied per label to the dog for the first time.<br>*14 June 2018: The dog starting excessively licking her rear end.<br>The dog has not been seen by the vet for her ongoing symptoms.<br>No further medical information available. |
| 20-Jun-2018 | UAE; 18US038371; MI; U.S.A | **Species:** Canine<br>**Breed:** Silky Terrier<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 12.00 Year(s)<br>**Weight:** 15 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 16-Jan-2018 | 17-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 20 Jun 2018, the owner reported the following event for Zena, 12 year old, 15 pound, intact female, Silky Terrier canine.<br>16 Jan 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60308AL) was applied between the shoulder blades.<br>17 Jan 2018: The pet experienced blisters and sore around the base of the tail.<br>Feb 2018*: The pet was presented to the clinic. The attending veterinarian prescribed Prednisone and Amoxicillin.<br>Unknown date: The pet recovered.<br>16 Jun 2018: Another vial was applied.<br>17 Jun 2018: The same symptoms occurred. The veterinarian refilled the prior prescription for Prednisone and Amoxicillin.<br>21 Jun 2018: Symptoms have improved but are still ongoing.<br>No further medical information is expected. |
| 20-Jun-2018 | UAE; 18US038545; IA; U.S.A | **Species:** Canine<br>**Breed:** Pointer<br>**Sex:** U | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | N/A | 01-Jun-2018* | 2 Day(s) | D-D | Suspected Adverse Event: On 20 Jun 2018, the owner reported the following event for Sadie, an English Pointer (all other signalments unknown). |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | 30 May 2018: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (R62001AR) was given to the dog topically (unknown site of application), by the owner. The dog was treated before on a monthly basis for an unknown amount of time.<br>1 Jun 2018*: The dog's skin was blistered at the site of application. The dog was itching and the fur started falling out.<br>The dog was not seen by a veterinarian or given any treatment.<br>The dog's current status is unknown. No further medical information expected. |
| 20-Jun-2018 | UAE; 18US038582; IA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Species not indicated / recommended) | N/A | 20-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 20 Jun 2018, the owner reported the following event for a feline (all signalments unknown).<br>19 Jun 2018: An unknown amount (approx. 1 CC) of FRONTLINE PLUS DOG (lot unknown, product unsubstantiated) was given to the cat topically between the shoulder blades, by the owner. The cat has been on the product for an unknown amount of time.<br>20 Jun 2018: The cat's eyes were dilated and the cat was drooling and vomiting.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected. |
| 21-Jun-2018 | UAE; 18US038659; IL; U.S.A | **Species:** Canine<br>**Breed:** Retriever Labrador<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 75 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 10-Apr-2018 | 10-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 21 June 2018, the owner reported the following event for Sargeant, a 3 year old, 75 pound, neutered male Retriever Labrador.<br>10 June 2018: The dog was treated with one vial of FRONTLINE PLUS DOG 45-88 LBS (P62005AR) (FL). Following the treatment the dog picked up fleas and started to pull his fur out.<br>The owner applied some itch spray to the dog to offer relief. The dog has been on FL for the past 2 months with no issues. No further medical information available. |
| 21-Jun-2018 | UAE; 18US038734; AR; U.S.A | **Species:** Canine<br>**Breed:** Australian Shepherd<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 14.00 Year(s)<br>**Weight:** 41 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-May-2017* | 31-May-2018 | 3 Week(s) | D-D | Suspected Adverse Event: On 21 Jun 2018, the owner reported the following event for Bobbie, 14 year old, 41 pound, spayed female, Australian Shepherd canine.<br>10 May 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (R61020AL) was applied between the shoulder blades.<br>31 May 2018: The pet experienced a hotspot at the application site. The pet was not presented to the clinic. The owner clipped the hair around the wound and applied Vaseline.<br>21 Jun 2018: Symptoms have improved but are still ongoing.<br>The pet has received the product sporadically since 1 May 2018 and the same symptoms occurred. No further medical information is expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 21-Jun-2018 | UAE; 18US038951; CA; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** F **Sex qualifier:** Neutered **Age:** 6.00 Year(s) **Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 28-Apr-2018 | 30-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 21 Jun 2018, the owner reported the following event for an unknown feline (all signalments unknown).<br>Unknown Date: An unknown amount of FRONTLINE PLUS CATS (lot unknown) was given to the cat topically (unknown site of application), by the owner. The cat has received the product before for an unknown amount of time. The owner stated each time she tried to apply the product, the cat moves around and doesn't like it. It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected.<br>UPDATE 22 Jun 2018: The owner reported the following for Ziggy, an approximately 6 year old, approximately 10 pound, spayed female.<br>28 Apr 2018: 1 vial of the product (R40801AW) was applied to the cat between the shoulder blades. The symptoms occurred while the owner was applying the product. The cat recovered after the application.<br>30 May 2018: The cat was given another dose of the product. The cat had the same symptoms.<br>The cat was not seen by a veterinarian or given any treatment. No further medical information expected. |
| 22-Jun-2018 | UAE; 18US039070; MO; U.S.A | **Species:** Canine **Breed:** Terrier (Jack Russell) **Sex:** M **Sex qualifier:** - **Age:** 5.00 Year(s) **Weight:** 20 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 15-Jun-2018* | 20-Jun-2018* | 5 Day(s) | D-D | Suspected Adverse Event: On 22 Jun 2018, the owner reported the following event for Barney, 5 year old, 20 pound, intact male, Jack Russell Terrier mix canine.<br>15 Jun 2018*: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied between the shoulder blades.<br>20 Jun 2018*: The pet experienced increased itching. The pet scratched himself to the point he started bleeding. The pet was not presented to the clinic and no treatment was provided.<br>22 Jun 2018: Symptoms are still ongoing.<br>There is one other dog in the household that also received the product and experienced symptoms (see case 18US039083). No further medical information is expected. |
| 22-Jun-2018 | UAE; 18US039083; -; U.S.A | **Species:** Canine **Breed:** Fox Terrier (Wire-Haired) **Sex:** M **Sex qualifier:** Neutered **Age:** 15.00 Year(s) **Weight:** 15 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 15-Jun-2018* | 20-Jun-2018* | 5 Day(s) | D-D | Suspected Adverse Event: On 22 Jun 2018, the owner reported the following event for Benny, 15 year old, 15 pound, intact male, Jack Russell Terrier mix canine.<br>15 Jun 2018*: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied between the shoulder blades.<br>20 Jun 2018*: The pet experienced increased itching. The pet scratched himself to the point he started bleeding. The pet was not presented to the clinic and no treatment was provided.<br>22 Jun 2018: Symptoms are still ongoing.<br>There is one other dog in the household that also received the product and experienced symptoms (see case 18US039070). No further medical information is expected. |
| 22-Jun-2018 | UAE; 18US039093; AZ; U.S.A | **Species:** Canine **Breed:** Pit Bull **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 49 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other | 21-May-2018 | 21-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 22 Jun 2018, the owner reported the following event for a 49 pound, Pit Bull canine (all other signalments unknown).<br>21 May 2018: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (M63906) was applied topically at an unknown location.<br>21 Jun 2018: Another vial was applied. The pet vomited 3 times. It is unknown if the pet was presented to the clinic or if any treatment was provided. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | 22 Jun 2018: The status of the pet is unknown.<br>Rocks were also found in the pets stomach. No further medical information is expected. |
| 22-Jun-2018 | UAE; 18US039102; PA; U.S.A | **Species:** Canine<br>**Breed:** Mixed Breeds / various<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 62 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 22-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 22 Jun 2018, the owner reported the following event for Riley, 62 pound, Mixed Breed canine (all other signalments unknown).<br>22 Jun 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was applied between the shoulder blades. The pet experienced vomiting. It is unknown if the pet was presented to the clinic or if any treatment was provided.<br>The pet has received the product on 2 prior unknown dates and the same symptoms presented. No further medical information is expected. |
| 22-Jun-2018 | UAE; 18US039125; MN; U.S.A | **Species:** Canine<br>**Breed:** Dachshund<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 3 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** FIPRONIL 9.8% / S-METHOPRENE 8.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Apr-2016* | 02-May-2018* | 31 Day(s) | D-D | Suspected Adverse Event: On 22 Jun 2018, the veterinary technician reported the following event for two Dachshunds of further unknown signalment.<br>1 May 2018*: The pet owner applied unknown FRONTLINE GOLD DOG (lot unknown) (product unsubstantiated), topically, in unknown locations.<br>2 May 2018*: Both dogs became pruritic.<br>1 Jun 2018*: Another application of unknown FRONTLINE GOLD DOG was applied to both canines despite their ongoing pruritus. Presently, both patients remain pruritic and neither have fleas .<br>There is a third Dachshund in the home who received FRONTLINE GOLD DOG without any issues. Since an unknown date in 2016 to 1 Apr 2018*, all three dogs received unknown FRONTLINE PLUS DOG (lot unknown) (product unsubstantiated), monthly, without any issues. Of the two affected dogs, one has unknown allergies and the other has unknown medical conditions that are ongoing.<br>No further medical information expected. |
| 22-Jun-2018 | UAE; 18US039260; MO; U.S.A | **Species:** Canine<br>**Breed:** Terrier (Jack Russell)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 8 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 15-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 22 Jun 2018, the owner reported the following event for Lucy, 10 year old, 8 pound, spayed female, Jack Russell Terrier canine.<br>15 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R6083AL) was applied between the shoulder blades. The pet experienced diarrhea and lethargy. The pet was not presented to the clinic and no treatment was provided.<br>23 Jun 2018: The pet recovered.<br>The pet has received the product on prior unknown dates and no symptoms presented. There is one other dog in the household that also received the product and was asymptomatic. No further medical information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 25-Jun-2018 | UAE; 18US039287; PA; U.S.A | **Species:** Canine **Breed:** French Bulldog **Sex:** F **Sex qualifier:** Neutered **Age:** 11.00 Year(s) **Weight:** 26 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Amoxicillin; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Treatment / vaccination program not respected) | 20-Jun-2008 | 23-Jun-2018 | 3 Day(s) | D-C | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for Jazzy, an 11 year old, 26 pound, spayed female, French Bulldog.<br>2008*: The dog started on 1 vial of FRONTLINE PLUS DOG 23-44 LBS (L64503) given to the dog topically from the shoulder blades to the tail. The dog was treated about once or twice a year around Jul and/or Sep.<br>11 Jun 2018: The dog started on Amoxicillin to treat Anaplasmosis.<br>20 Jun 2018: The owner applied another dose of the product.<br>23 Jun 2018: The dog was given another dose of Amoxicillin. The dog had hives down her back, on her sides, and legs.<br>The dog was not seen by a veterinarian or given any treatment.<br>The symptoms are ongoing. No further medical information expected. |
| 25-Jun-2018 | UAE; 18US039309; OH; U.S.A | **Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** - **Weight:** 5 lbs* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 25-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for a 5 pound, neutered male, Domestic Longhair feline (all other signalments unknown).<br>25 Jun 2018: An unknown amount of FRONTLINE PLUS CATS (R4101GRW) was applied topically at a unknown location. The pet began vomiting every 2-3 hours. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 25-Jun-2018 | UAE; 18US039422; TX; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 3.00 Year(s) **Weight:** 12 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 21-May-2018 | 21-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for a Chihuahua canine (all other signalments unknown).<br>Unknown date: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (M63306) was applied between the shoulder blades. The pet experienced burning all over the body. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected.<br>Update 5 Jul 2018: The owner called to report event for Precious, 3 year old, 12 pound, spayed female, Chihuahua canine.<br>21 Jun 2018: One vial of FRONTLINE DOG 5-22 LBS was applied between the shoulder blades. The pet experienced intense itching all over the body like the product was burning. The pet was not presented to the clinic and no treatment was provided.<br>24 Jun 2018: The pet recovered.<br>The pet received the product on 21 May 2018 and no symptoms presented. No further medical information is expected. |
| 25-Jun-2018 | UAE; 18US039431; OH; U.S.A | **Species:** Feline **Breed:** Siamese **Sex:** F **Sex qualifier:** Neutered **Age:** 17.00 | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products** | N/A | 23-Jun-2018 | 0 Day(s) | D-A | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for Sassy, 17 year old, 6 pound, spayed female, Siamese feline.<br>23 Jun 2018: One third of a vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. The pet experienced foaming at the mouth and vomiting. It is believed that the pet ingested the product. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | Year(s)<br>**Weight:** 6 lbs | | | | **used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Low dose) | | | | | 24 Jun 2018: The pet was presented to the clinic. It is unknown if any treatment was provided.<br>25 Jun 2018: Symptoms are still ongoing.<br>The pet received FRONTLINE on prior unknown dats and no symptoms presented. There are two other cats in the household that also had the product and experienced symptoms (see case 18US039756, 18US039758). No further medical information is expected.<br>UPDATE 26 Jun 2018: Owner called to report symptoms have worsened. The pet is experiencing anorexia, and lethargy. The cat is still at the clinic in the intensive care unit. The attending veterinarian is treating with fluids and unknown medications. No further medical information is expected.<br>UPDATE 25 Jul 2018: Per information reported by the retailer, the cat is now deceased. It is unknown the circumstances under which the cat expired.<br>No further information is available at this time. |
| 25-Jun-2018 | UAE;<br>18US039450;<br>CA; U.S.A | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 14 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 05-May-2018* | 06-Jun-2018* | 1 Day(s) | D-D | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for Panda, a 6 year old, approximately 14 pound, neutered male, Small Crossbreed (<10kg).<br>5 May 2018*: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60509AL) was given to the dog top of the neck and around the tail. Approximately a day later, the dog was vomiting and lethargic and had redness at the application site. The dog recovered after about 2 days.<br>5 Jun 2018*: The dog was given another application of the product.<br>6 Jun 2018*: The dog had the same symptoms.<br>8 Jun 2018*: The dog recovered.<br>The dog was seen by the veterinarian but was not given any treatment. The dog has had a skin rash while using Advantage before. No further medical information expected. |
| 25-Jun-2018 | UAE;<br>18US039515;<br>MO; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 10 lbs | 3 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 22-Jun-2018* | 22-Jun-2018* | 0 Day(s) | D-B | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for a 10 pound, feline (all other signalments unknown).<br>22 Jun 2018: An unknown amount (approximately 1 cc) of FRONTLINE PLUS DOG (lot unknown, product unsubstantiated) was given to the cat topically (unknown site of application), by the owner. On an unknown date following the application, the cat may have had a stroke or exhibited symptoms of a brain infection. The cat is lethargic, can't walk and is crying in pain.<br>The cat was seen by the veterinarian and given an unknown treatment. The symptoms are ongoing. No further medical information expected. |
| 25-Jun-2018 | UAE;<br>18US039543;<br>MA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Longhair (Crossbreed) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | 21-Jun-2003* | 21-Jun-2018* | 0 Day(s) | D-C | Suspected Adverse Event: On 25 June 2018, the owner reported the following event for Bentley, a 15 year old, 10 pound, neutered male Domestic Longhair.<br>*21 June 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was topically applied per label to the cat. Following the |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 15.00 Year(s)<br>**Weight:** 10 lbs | | | | 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | treatment the cat looked like he was on fire, he was red, missing hair, and he was uncomfortable.<br>*22 June 2018: The cat had a seizure and was taken to the vet and he was given Prednisone shot.<br>The cat recovered on an unknown date. The cat has been on FL all his life with no issues. No further medical information available. |
| 25-Jun-2018 | UAE; 18US039562; NJ; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 01-Jan-2017* | N/A | D-C | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for a Domestic Shorthair feline (all other signalments unknown).<br>Unknown 2017: One vial of FRONTLINE PLUS CATS (M40901AW) was applied between the shoulder blades. The pet experienced lethargy and weight loss. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 25-Jun-2018 | UAE; 18US039648; NY; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 24-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for a Canine (all other signalment unknown).<br>24 Jun 2018: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was applied topically at a unknown location. The pet experienced hypersalivation. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 25-Jun-2018 | UAE; 18US039700; TX; U.S.A | **Species:** Canine<br>**Breed:** Bulldog<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 60 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 19-May-2018 | 13-Jun-2018* | 3 Day(s) | D-D | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for Ruby, 7 year old, 60 pound, spayed female, Bulldog canine.<br>19 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>10 Jun 2018: Another vial was applied.<br>13 Jun 2018*: The pet experienced intense itching and biting. The pet was not presented to the clinic and no treatment was provided.<br>26 Jun 2018: Symptoms are still ongoing.<br>There are 3 other dogs in the household that received the product and experienced symptoms (see case 18US039995, 18US040001, 18US040009). No further medical information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| 25-Jun-2018 | UAE; 18US039711; CA; U.S.A | **Species:** Feline **Breed:** Maine Coon Cat **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 22-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On ( Date), the owner reported the following event for a Maine Coon Feline (all other signalments unknown).<br>22 Jun 2018: An unknown amount of FRONTLINE PLUS CAT (lot unknown) was applied topically at a unknown location. The pet experienced strange behavior and lethargy. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the cat is unknown.<br>No further medical information is expected. |
| 26-Jun-2018 | UAE; 18US039756; OH; U.S.A | **Species:** Feline **Breed:** Siamese **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 7 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | 23-Jun-2018 | 23-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for Braxton, 1 year old, 7 pound, neutered male, Siamese feline.<br>23 Jun 2018: One third of a vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. The pet experienced vomiting.<br>24 Jun 2018: The pet was not presented to the clinic and no treatment was provided.<br>25 Jun 2018: Symptoms are still ongoing.<br>There are two other cats in the household that also had the product and experienced symptoms (see case 18US039431, 18US039758). No further medical information is expected.<br>UPDATE 26 Jun 2018: Owner called to report pet recovered. No further medical information is expected. |
| 26-Jun-2018 | UAE; 18US039758; OH; U.S.A | **Species:** Feline **Breed:** Siamese **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 7 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** Unknown antibiotic; **Route:** Topical / Cutaneous **Was the product used ok?:** No (Low dose) | 23-Jun-2018 | 23-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for Brodie, 1 year old, 7 pound, neutered male, Siamese feline.<br>23 Jun 2018: One third of a vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. The pet experienced vomiting.<br>24 Jun 2018: The pet was not presented to the clinic and no treatment was provided.<br>25 Jun 2018: Symptoms are still ongoing.<br>The pet is also receiving an unknown antibiotic due to flea allergy dermatitis. There are two other cats in the household that also had the product and experienced symptoms (see case 18US039431, 18US039756). No further medical information is expected.<br>UPDATE 26 Jun 2018: Owner called to report pet recovered. No further medical information is expected. |
| 26-Jun-2018 | UAE; 18US039806; CA; U.S.A | **Species:** Canine **Breed:** German Shepherd Dog **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 60 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used** | 22-Jun-2018* | 26-Jun-2018* | 4 Day(s) | D-D | Suspected Adverse Event: On 26 June 2018, the owner reported the following event for a 60 pound German Shepherd (signalment unknown).<br>22 June 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (G67201AR) was applied to the dog.<br>On an unknown date the dog developed skin irritation the size of a silver dollar. No further medical information available. |

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| | | | | | | **ok?:** Unknown to Company | | | | | |
| 26-Jun-2018 | UAE; 18US039812; IL; U.S.A | **Species:** Canine **Breed:** Retriever (Labrador, Chocolate) **Sex:** U **Sex qualifier:** Unknown **Age:** 10.00 Month(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 20-Jun-2018* | 26-Jun-2018* | 6 Day(s) | D-D | Suspected Adverse Event: On 26 June 2018, the owner reported the following event for a Chocolate Lab (signalment unknown).<br>*20 June 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied to the dog.<br>*26 June 2018: The dog developed a rash on its stomach.<br>No further medical information available.<br>UPDATE 10 Jul 2018: At the time of the report, the pet owner reported that fleas were observed on the pet and believes they may be the cause of the rash observed. No further medication information expected. |
| 22-Jun-2018 | UAE; 18US039816; PA; U.S.A | **Species:** Canine **Breed:** Mixed Breeds / various **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 85 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | N/A | 22-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 22 Jun 2018, the owner reported the following event for Duncan, 85 pound, Mixed Breed canine.<br>22 Jun 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was applied between the shoulder blades. The pet experienced vomiting. It is unknown if the pet was presented to the clinic or if any treatment was provided.<br>The pet has received the product on 2 prior unknown dates and no symptoms presented. No further medical information is expected. |
| 26-Jun-2018 | UAE; 18US039927; MI; U.S.A | **Species:** Feline **Breed:** Domestic Longhair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 4.00 Year(s) **Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Dec-2014* | 25-Dec-2017* | 10 Month(s) 3 Week(s) | D-D | Suspected Adverse Event: On 26 Jun 2018, the owner reported the following event for Catniss, an approximately 4 year old, approximately 10 pound, spayed female, Domestic Longhair (Crossbreed).<br>2014*: The cat started on 1 vial of FRONTLINE PLUS CATS (lot unknown) was given to the cat topically between the shoulder blades, by the owner. The cat was treated monthly on a year round basis.<br>1 Dec 2017*: The owner applied another dose of the product.<br>25 Dec 2017*: The owner started noticing fleas on the cat. The cat had fleas bites all over the body and was losing hair all over the body.<br>1 Jan 2018*: The owner applied another dose of the product.<br>1 Feb 2018*: The owner used the last dose of the product.<br>1 Mar 2018*: The owner switched to Bravecto and the fleas went away and symptoms stopped.<br>The cat was seen by a veterinarian and given Depo-medrol and Convenia. No further medical information expected. |
| 26-Jun-2018 | UAE; 18US039938; CA; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other | 01-Jun-2018* | 01-Jun-2018* | 0 Day(s) | D-B | Suspected Adverse Event: On 26 June 2018, the owner reported the following event for a cat (signalment unknown).<br>*1 June 2018: The cat was treated with FRONTLINE PLUS CATS (lot unknown) and following the treatment the cat went into shock and collapsed with seizure like activity.<br>The owner declined the report. No further medical information expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** Unknown | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | |
| 25-Jun-2018 | UAE; 18US039995; TX; U.S.A | **Species:** Canine<br>**Breed:** Bulldog<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 50 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 19-May-2018 | 13-Jun-2018* | 3 Day(s) | D-D | Suspected Adverse Event: On 26 Jun 2018, the owner reported the following event for Fanny Mae, 6 year old, 50 pound, spayed female, Bulldog canine.<br>19 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>10 Jun 2018: Another vial was applied.<br>13 Jun 2018*: The pet experienced intense itching and biting. The pet was not presented to the clinic and not treatment was provided.<br>26 Jun 2018: Symptoms are still ongoing.<br>There are 3 other dogs in the household that received the product and experienced symptoms (see case 18US039700, 18US040001, 18US0). No further medical information is expected. |
| 26-Jun-2018 | UAE; 18US040001; TX; U.S.A | **Species:** Canine<br>**Breed:** Bulldog<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 8.00 Year(s)<br>**Weight:** 50 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination program not respected) | 19-May-2018 | 13-Jun-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 26 Jun 2018, the owner reported the following event for Lily, 8 year old, 50 pound, spayed female, Bulldog canine.<br>19 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>10 Jun 2018: Another vial was applied.<br>13 Jun 2018*: The pet experienced intense itching and biting. The pet was not presented to the clinic and no treatment was provided.<br>26 Jun 2018: Symptoms are still ongoing.<br>There are 3 other dogs in the household that received the product and experienced symptoms (see case 18US039700, 18US039995, 18US040009). No further medical information is expected. |
| 25-Jun-2018 | UAE; 18US040009; -; U.S.A | **Species:** Canine<br>**Breed:** Shar Pei<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 14.00 Year(s)<br>**Weight:** 50 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Treatment / vaccination | 19-May-2018 | 13-Jun-2018* | 3 Day(s) | D-D | Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for Tipe, 14 year old, 50 pound, intact male, Shar Pei Canine.<br>19 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>10 Jun 2018: Another vial was applied.<br>13 Jun 2018*: The pet experienced intense itching and biting. The pet was not presented to the clinic and not treatment was provided.<br>26 Jun 2018: Symptoms are still ongoing.<br>There are 3 other dogs in the household that received the product and experienced symptoms (see case 18US039995, 18US040001, 18US039700). No further medical information is expected. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | program not respected) | | | | | |
| 27-Jun-2018 | UAE; 18US040020; RI; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - **Weight:** 12 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 02-Jun-2018* | 03-Jun-2018* | 1 Day(s) | D-C | Suspected Adverse Event: On 26 June 2018, the owner reported the following event for a 12 pound dog (signalment unknown) 2 June 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied to the dog. The dog has fleas and on an unknown date started to gnaw at himself and the dog also got a really bad ear infection after the application. No further medical information available. |
| 26-Jun-2018 | UAE; 18US040086; FL; U.S.A | **Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Unknown to Company | 19-Jun-2018 | 20-Jun-2018 | 1 Day(s) | D-B | Suspected Adverse Event: The following event was reported on 26 June 2018 for Ripley, an unknown age, female Pit Bull. 19 June 2018 : At approximately 8:30 pm on this date, the pet owner applied FRONTLINE PLUS DOG 45-88 LBS (lot unknown) to the pet. 20 June 2018: At approximately 3:30 am on this date, the pet began to have seizures, which continued every -3-4 hours. The pet owners presented the pet to the veterinary clinic and the pet received an IM and IV injection of Valium. The pet was then sent to an emergency clinic for monitoring of the seizures that were continuing to occur. It is unknown as to the current condition of this pet and it is unknown if the pet has a prior history of having seizures. No other medical information is expected. UPDATE 28 June 2018: The owner reported on a social media page that the pet had made several visits to their regular veterinarian and also to an emergency vet. The pet has stopped having seizures since being prescribed Keppra which is to be given BID for up to 6 months. No other medical information is expected. |
| 26-Jun-2018 | UAE; 18US040088; PA; U.S.A | **Species:** Canine **Breed:** Chihuahua **Sex:** F **Sex qualifier:** Neutered **Age:** 2.00 Year(s) **Weight:** 5 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 26-Jun-2018 | 26-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 26 June 2018, the owner reported the following event for Lady, a 2 year old, 5 pound, spayed female Chihuahua/Yorkie mix. 26 June 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was topically applied to the dog per label. Within half an hour the dog started to dry heave and she was lethargic. The owner washed the site with warm water and soap and the dog symptoms improved, but are still ongoing. No further medical information available. |
| 27-Jun-2018 | UAE; 18US040139; -; U.S.A | **Species:** Feline **Breed:** Feline (unknown) **Sex:** U **Sex qualifier:** Unknown **Age:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other | N/A | 01-Jan-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 27 Jun 2018, the owner reported the following event for a Feline (all other signalments unknown). Unknown date: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. The pet ingested the product and experienced anorexia. The pet was presented to the clinic. The bloodwork came back within normal limits. It is unknown if if treatment was provided. The status of the |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Weight:** Unknown | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | pet is unknown.<br>No further medical information is expected. |
| 27-Jun-2018 | UAE; 18US040152; IN; U.S.A | **Species:** Feline<br>**Breed:** Domestic Longhair (Crossbreed)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 25-Jun-2018* | 25-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 27 June 2018, the owner reported the following event for a Domestic Longhair (Crossbreed) (all other signalments unknown).<br>25 Jun 2018: 1 vial of FRONTLINE PLUS CATS (lot invalid) was given to the cat topically (unknown site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the cat was dry heaving, lethargic, had a runny nose and dry tongue.<br>It is unknown if the cat was seen by a veterinarian or given any treatment. The cat's current status is unknown. No further medical information expected. |
| 28-Jun-2018 | UAE; 18US040266; SC; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** 70 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 01-Feb-2018 | 01-Jun-2018 | 0 Day(s) | D-D | Suspected Lack of Efficacy Claim: On 27 Jun 2018, the owner reported the following event for a 70 pound, canine (all other signalment unknown)<br>1 Jun 2018: An unknown amount of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied topically at a unknown location. The pet experienced intense itching and chewing. It is unknown if the pet was presented to the clinic or if any treatment was provided.<br>The pet has received the product since 1 Feb 2018, it is unknown if symptpoms presented. There are 2 other dog in the household that also received the product and experienced symptoms (see case 18US042302, 18US042304). No further medical information is expected. |
| 27-Jun-2018 | UAE; 18US040299; CA; U.S.A | **Species:** Canine<br>**Breed:** Papillon<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 8 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 05-Jun-2018 | 19-Jun-2018 | 2 Week(s) | D-D | Suspected Adverse Event: On 27 Jun 2018, the owner reported the following event for Cirilio, 3 year old, 8 pound, neutered male, Papillon canine.<br>5 Jun 2018: 2/3 of a vial of FRONTLINE PLUS DOG 5-22 LBS (R60509AL) was applied between the shoulder blades.<br>19 Jun 2018: The pet experienced itching and hair loss around the base of the tail. The hair loss was due to obsessive chewing. The pet was not presented to the clinic and no treatment was provided.<br>27 Jun 2018: The symptoms are still ongoing.<br>No further medical information is expected. |
| 27-Jun-2018 | UAE; 18US040353; WI; U.S.A | **Species:** Canine<br>**Breed:** Siberian Husky<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 13.50 Year(s) | 8 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** | 15-Jun-2005* | 01-May-2018* | N/A | D-C | Suspected Adverse Event: On 27 Jun 2018, the owner reported the following event for Dream, a 13.5 year old, approximately 40 pound, non-pregnant non-lactating intact female, Siberian Husky.<br>2005*: The dog started on 1 vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was given to the dog topically between the shoulder blades, by the owner. The dog also started on IVOMEC liquid orally (product unsubstantiated). The dog was treated with |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | **Weight:** 40 lbs | | | | Prednisone; IVERMECTIN 10 MG/ML SOLUTION FOR INJECTION; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | | | | | both products monthly on a seasonal basis from Apr -Nov.<br>May 2018*: The dog started on Prednisone to treat a possible cancerous mass near her heart. The dog was treated every morning.<br>18 May 2018: The last dose of IVOMEC (BV135/12, 2 Mar 2017, product unsubstantiated) was given.<br>15 Jun 2018: The last dose of FRONTLINE PLUS DOG 23-44 LBS was given.<br>18 Jun 2018: The dog received another dose of Prednisone. The dog had scabbed skin at the application site and was losing fur.<br>20 Jun 2018: The dog recovered.<br>The dog was seen by a veterinarian and given Simplicef. The owner gave the dog a bath. No further medical information expected.<br>UPDATE 13 Jul 2018: Received unused FRONTLINE PLUS DOG 23-44 LBS product, lot number is P60505AL. |
| 27-Jun-2018 | UAE; 18US040366; MI; U.S.A | **Species:** Canine **Breed:** Retriever (Golden) **Sex:** F **Sex qualifier:** Neutered **Age:** 8.00 Year(s) **Weight:** 70 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Jun-2010* | 22-Jun-2018* | 9 Day(s) | D-D | Suspected Adverse Event: On 27 Jun 2018, the owner reported the following event for Pipper, 8 year old, 70 pound, spayed female, Golden Retriever mix canine.<br>13 Jun 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R60206AR) was applied between the shoulder blades.<br>22 Jun 2018*: The dog experienced intense itching near the base of the tail. The pet was not presented to the clinic and no treatment was provided.<br>27 Jun 2018: The symptoms are still ongoing.<br>The pet has received the product monthly since 1 Jun 2010* and no symptoms presented. No further medical information is expected. |
| 27-Jun-2018 | UAE; 18US040376; PA; U.S.A | **Species:** Canine **Breed:** Retriever Labrador **Sex:** M **Sex qualifier:** Unknown **Age:** - **Weight:** 120 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Apr-2018* | 01-Apr-2018* | N/A | D-D | Suspected Adverse Event: On 14 Jun 2018 the pet owner reported the following event via mail for Bear, a 120 pound male Labrador Retriever of unknown further signalment.<br>*Apr 2018: Started on FRONTLINE PLUS DOG 89-132 LBS (lot number unknown) once monthly. At an unknown time following application the dog began exhibiting pruritus. The pet owner states there is no indication of fleas on the dog.<br>The pet owner states the dog becomes pruritic after the last 3 applications each month. It is unknown if the dog has received treatment or if he has recovered.<br>No further medical information is expected. |
| 27-Jun-2018 | UAE; 18US040379; SD; U.S.A | **Species:** Canine **Breed:** Canine (unknown) **Sex:** F **Sex qualifier:** Unknown **Age:** - **Weight:** 75 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** unknown **Was the product used ok?:** Unknown to Company | 01-Jun-2018* | 02-Jun-2018* | 1 Day(s) | D-D | Suspected Adverse Event: On 13 Jun 2018 the pet owner reported via mail the following event for a 75 pound, female Italian Spinone canine of unknown further signalment.<br>*1 Jun 2018: The pet owner applied an unknown amount of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) to an unknown area.<br>*2 Jun 2018: The dog vomited, became lethargic, and exhibited redness around both eyes. It is unknown if the reaction was treated or if the dog has recovered.<br>The pet owner reported another reaction for the same dog (see case number 18US040562). No further information is available at this time. |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| 27-Jun-2018 | UAE; 18US040451; MI; U.S.A | **Species:** Canine **Breed:** Shetland Sheep Dog (Sheltie) **Sex:** M **Sex qualifier:** - **Age:** 14.00 Year(s) **Weight:** 38 lbs | 1 | 1 | 1 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** Sentinel or Interceptor; **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Sep-2010* | 01-Oct-2014* | 4 Year(s) | D-A | Suspected Adverse Event: On 27 June 2018, the owner reported the following event for Benny, a 14 year old, 38 pound, intact male Shetland Sheep Dog.<br>*1 Oct 2010: One dose of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown) was applied to the dog per label.<br>*1 Oct 2014: The dog developed a tumor at his neck that never went away.<br>*1 May 2018: The dog died of cancer.<br>The dog had FL the month prior with no issues. The dog also was either on Sentinel or Interceptor at the time. No further medical information expected. |
| 27-Jun-2018 | UAE; 18US040457; OR; U.S.A | **Species:** Feline **Breed:** Siamese **Sex:** U **Sex qualifier:** Unknown **Age:** 8.00 Year(s) **Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 02-Jul-2010* | 02-Jul-2017* | 0 Day(s) | D-D | Suspected Adverse Event: On 27 Jun 2018, the owner reported the following event for an unknown number of Siamese felines (all other signalments unknown).<br>Unknown date: An unknown amount of FRONTLINE PLUS CATS (lot unknown) was given to the cats (unknown route and site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application, the cats acted like they were being burned and were running around.<br>It is unknown if the cats were seen by a veterinarian or given any treatment. The cats' current status is unknown. No further medical information expected.<br>UPDATE 2 Jul 2018: The owner reported the following for two, 8 year old, Siamese felines (all other signalments unknown).<br>2010*: The cats started on 1 vial of the product given topically between the shoulder blades. The cats were only treated as needed.<br>Jul 2017*: The cats received another dose of the product and the symptoms started that same day. The owner also noticed the skin was red at the application site on both cats. The cats recovered after about 1 week.<br>Jul 2018*: The cats were treated again and did not have any symptoms.<br>The cats were not seen by a veterinarian or given any treatment.<br>No further medical information expected. |
| 27-Jun-2018 | UAE; 18US040460; WA; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 20.00 Year(s) **Weight:** 9 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 21-Jun-2018 | 22-Jun-2018 | 1 Day(s) | D-C | Suspected Adverse Event: On 27 June 2018, the owner reported the following event for Pager Ban, a 9 pound, 20 year old, neutered male Domestic Shorthair.<br>21 June 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied to the cat per label for the first time.<br>22 June 2018: The cat had hairloss a the application site, fever, kidney function issues, weight loss, vomiting, lethargy, inflamed skin, and dehydration. The vet came to the home and treated the cat with saline, IV fluids, and unknown antibiotics.<br>28 June 2018: The cat is doing better.<br>No further medical information available |
| 28-Jun-2018 | UAE; 18US040465; VA; U.S.A | **Species:** Canine **Breed:** Yorkshire Terrier **Sex:** U **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | 26-Jun-2018* | 26-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 28 Jun 2018, the owner reported the following event for a Yorkshire Terrier (all other signalments unknown).<br>26 Jun 2018: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was given to the dog (unknown route and site of application), by the groomer. It is unknown if this was the |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | **Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | first dose applied. Within an hour of the application, the dog vomited.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected. |
| 28-Jun-2018 | UAE; 18US040494; VA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 14.00 Year(s)<br>**Weight:** 10 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 27-Jun-2018 | 0 Day(s) | D-C | Suspected Adverse Event: On 28 Jun 2018, the owner reported the following event for Sunjay, 14 year old, 10 pound, neutered male, Domestic Shorthair feline.<br>27 Jun 2018: One vial of FRONTLINE PLUS CATS (R41058AW) was applied between the shoulder blades. After a few hours the pet experienced lethargy, inability to walk, and dilated pupils . The pet was not presented to the clinic. The owner bathed the pet in Dawn.<br>27 Jun 2018: Symptoms are still ongoing.<br>The cat received the product on prior unknown dates and no symptoms presented. There is a dog in the household that also received the FRONTLINE and experienced symptoms (see case 18US040528). No further medical information is expected. |
| 28-Jun-2018 | UAE; 18US040506; AZ; U.S.A | **Species:** Canine<br>**Breed:** Mixed Breeds / various<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 45 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 27-Jun-2018 | 27-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 28 Jun 2018 , the owner reported the following event for Patriot, 45 pound, Mixed breed canine (all other signalments unknown).<br>27 Jun 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) was applied between the shoulder blade. The product appeared to burn the pet. The pet began growling after application. The pet was not presented to the clinic and no treatment was provided.<br>28 Jun 2018: The pet recovered.<br>The pet has reacted to a unknown flea topical in the past. No further medical information is expected. |
| 28-Jun-2018 | UAE; 18US040528; VA; U.S.A | **Species:** Canine<br>**Breed:** Mixed Breeds / various<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 10.00 Year(s)<br>**Weight:** 70 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | N/A | 01-Jan-2010 | 0 Day(s) | D-C | Suspected Adverse Event: On 28 Jun 2018, the owner reported the following event for Hobe, 10 year old, 70 pound, neutered male, Mixed Breed canine.<br>Unknown date: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades. After a couple months the pet presented neurological signs. The pet was presented to the clinic and diagnosed with Vestibular disease . It is unknown if any treatment was provided. The status of the pet is unknown<br>There is a cat in the household that also received the FRONTLINE and experienced symptoms (see case 18US040494). No further medical information is expected. |
| 28-Jun-2018 | UAE; 18US040562; SD; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** F<br>**Sex qualifier:** Unknown<br>**Age:** - | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other | 01-Jun-2018* | 07-Jun-2018* | 6 Day(s) | D-D | Suspected Lack of Efficacy Claim: On 13 Jun 2018 the pet owner reported via mail the following event for a 75 pound, female Italian Spinone canine of unknown further signalment.<br>*1 Jun 2018: The pet owner applied an unknown amount of FRONTLINE PLUS DOG 45-88 LBS (R61201BR) to an unknown area.<br>*7 Jun 2018: The pet owner reported finding an unknown number |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Weight:** 75 lbs | | | | products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | | | | | of ticks on the dog.<br>*14 Jun 2018: The pet owner reported finding 50 ticks on the dog. It is unknown if there are other dogs in the household and if they are on a flea and tick product. The pet owner reported an adverse reaction for the same dog (see case number 18US040379). No further information is available at this time. |
| 28-Jun-2018 | UAE; 18US040708; TX; U.S.A | **Species:** Feline<br>**Breed:** Calico<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 20-Jun-2018* | 1 Day(s) | D-D | Suspected Adverse Event: On 28 Jun 2018, the owner reported the following event for Callie Buttercup, Calico Feline (all other signalments unknown).<br>19 Jun 2018: One vial of FRONTLINE PLUS CATS (R41105AW) was applied between the shoulder blades.<br>Unknown date: The pet presented irritation and aggression toward the pet owner. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 28-Jun-2018 | UAE; 18US040751; AL; U.S.A | **Species:** Canine<br>**Breed:** Large crossbred (>20 Kg)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 57.9 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** AFOXOLANER 136 MG CHEWABLE TABLETS;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jan-2016* | 23-Jun-2018 | 1 Week(s) | D-D | Suspected Adverse Event: On 28 Jun 2018, a clinic staff reported the following event for Kaya, a 6 year old (1 Apr 2012*), 57.9 pound, spayed female Large crossbred.<br>18 Jun 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades.<br>22 Jun 2018: 1 chew of NEXGARD (136 MG) (lot and expiration unknown) was given to the dog for the first time. The dog weighed 61 pounds.<br>23 Jun 2018: The owner noted a rash on the dog's belly and treated the dog with Benadryl.<br>25 Jun 2018: The dog vomited. The owner's yard was sprayed for fleas as well.<br>28 Jun 2018: The dog presented to the clinic with continued symptoms and was treated with an injection of Cerenia and metronidazole.<br>Kaya has received FRONTLINE PLUS prior on unknown dates with no issues.<br>No further medical information expected. |
| 28-Jun-2018 | UAE; 18US040782; OR; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Neutered<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | N/A | 28-Jun-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 28 Jun 2018, the owner reported the following event for a Feline (all other signalment).<br>Unknown date: An unknown amount of FRONTLINE PLUS CATS (lot unknown) was applied topically at a unknown location. The pet experienced irritation at the application site. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected. |
| 28-Jun-2018 | UAE; 18US040807; VT; U.S.A | **Species:** Canine<br>**Breed:** Yorkshire Terrier | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 28-May-2017* | 21-Jun-2018 | 24 Day(s) | D-D | Suspected Adverse Event: On 28 June 2018, the owner reported the following event for Buddy, a 12 year old, 20 pound, neutered male Yorkie. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 12.00 Year(s)<br>**Weight:** 20 lbs | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Overdose) | | | | | 28 May 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (R60516BL) was topically applied per label to the dog.<br>21 June 2018: The dog started to itch and dig without the presence of fleas.<br>The dog does have dry skin issues and have itching spells. The dog has been on FL at least for the past year with no issues. No further medical information available. |
| 28-Jun-2018 | UAE; 18US040808; MI; U.S.A | **Species:** Canine<br>**Breed:** Bull-Mastiff<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** Carprofen;<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 15-Jun-2018 | 16-Jun-2018* | 1 Day(s) | D-C | Suspected Adverse Event: On 28 Jun 2018, the owner reported the following event for Cocoa, Bull Mastiff canine (all other signalments unknown).<br>15 Jun 2018: One vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) was applied between the shoulder blades.<br>Unknown date: The pet experienced wobbly gait and inability to move front legs. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown. The pet received their last dose of Carprofen 10 Jun 2018. No further medical information is expected. |
| 28-Jun-2018 | UAE; 18US040809; NC; U.S.A | **Species:** Canine<br>**Breed:** Pit Bull<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 10.00 Year(s)<br>**Weight:** 40 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Overdose) | 28-May-2017* | 21-Jun-2018 | 24 Day(s) | D-D | Suspected Adverse Event: On 28 June 2018 the owner reported the following event for Lika, a 10 year old, 40 pound, intact female Pit Bull.<br>28 May 2018: One vial of FRONTLINE PLUS DOG 45-88 LBS (P63312DR) was applied to the dog to the skin between the shoulder blades.<br>21 June 2018: The dog started to lick, dig, and lose fur at her tail area.<br>The dog hasn't; been seen by the vet and the owner is monitoring her condition. The dog does suffer from FAD and has been on FL for years. No further medical information available. |
| 28-Jun-2018 | UAE; 18US040811; GA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 28-Jun-2018 | 28-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 28 June 2018, the owner's son reported the following event for a cat of unknown signalnent.<br>28 June 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied to the cat, the cat licked the application site and started to foam at the mouth.<br>No further medical information available. |
| 28-Jun-2018 | UAE; 18US040815; | **Species:** Canine<br>**Breed:** Terrier | 1 | 1 | 0 | **Product used:** FIPRONIL | 26-May-2018 | 26-May-2018* | N/A | D-D | Suspected Adverse Event: On 28 June 2018, the owner reported the following event for Dougie, a 5 year old, 15 pound, neutered |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | CA; U.S.A | Breeds (500 Series)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 5.00 Year(s)<br>**Weight:** 15 lbs | | | | 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | male Terrier.<br>26 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R61201) was applied to the dog for the first time.<br>On an unknown date the dog started to lose fur at the application site.<br>26 June 2018: The dog was given another treatment of FL and the hair loss continued.<br>The dog has not been seen by the vet and the owner is monitoring the dog's condition. There is one other treated dog in the home who also had the same reaction. See case 18US040925. No further medical information available. |
| 29-Jun-2018 | UAE; 18US040835; FL; U.S.A | **Species:** Canine<br>**Breed:** Small crossbred (<10 Kg)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 12 lbs | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 25-Jun-2018 | 25-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 29 Jun 2018, the owner reported the following event for Lexi, 6 year old, 12 pound, spayed female, Mixed Breed canine.<br>25 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades. The pet experienced irritation at the application site. The area was hot to touch. It is unknown if the pet was presented to the clinic or if any treatment was provided.<br>There is one other dog in the household that also received the product and is asymptomatic. No further medical information is expected. |
| 29-Jun-2018 | UAE; 18US040864; TN; U.S.A | **Species:** Canine<br>**Breed:** Shih Tzu<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 11 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jun-2014* | 26-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event:On 29 Jun 2018, the owner reported the following event for Lily Lou, 4 year old, 11 pound, spayed female, Shih Tzu canine.<br>25 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P60712) was applied between the shoulder blades.<br>26 Jun 2018: The pet experienced a burn at the application site. The pet was not presented to the clinic. The owner bathed the pet and applied an unknown ointment.<br>29 Jun 2018: Symptoms are still ongoing.<br>The pet has received the product since 1 Jun 2014* and no symptoms presented. There is one other dog in the household that also received the product (see case 18US040956). No further medical information is expected. |
| 29-Jun-2018 | UAE; 18US040899; PA; U.S.A | **Species:** Feline<br>**Breed:** Feline (unknown)<br>**Sex:** F<br>**Sex qualifier:** -<br>**Age:** 2.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 28-Jun-2018 | 28-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 29 Jun 2018, the owner reported the following event for Sissy, a 2 year old, intact female, feline (all other signalments unknown).<br>28 Jun 2018: 1 vial of FRONTLINE PLUS CATS (R41105AW) was given to the cat topically between the shoulder blades, by the owner. This was the first dose applied. That evening, the cat was itching and fur was falling out. The cat also vomited.<br>The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected. |
| 28-Jun-2018 | UAE; 18US040925; CA; U.S.A | **Species:** Canine<br>**Breed:** Cockapoo<br>**Sex:** M<br>**Sex qualifier:** Neutered | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | 26-May-2018 | 26-May-2018* | N/A | D-D | Suspected Adverse Event: On 28 June 2018, the owner reported the following event for Weddle, a 9 year old, 17 pound, neutered male Cockapoo.<br>26 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R61201) was applied to the dog for the first time. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Age:** 9.00 Year(s)<br>**Weight:** 17 lbs | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | On an unknown date the dog started to lose fur at the application site.<br>26 June 2018: The dog was given another treatment of FL and the hair loss continued.<br>The dog has not been seen by the vet and the owner is monitoring the dog's condition. There is one other treated dog in the home who also had the same reaction. See case 18US040815. No further medical information available. |
| 29-Jun-2018 | UAE; 18US040945; IL; U.S.A | **Species:** Canine<br>**Breed:** Schnauzer (Miniature)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 9.00 Year(s)<br>**Weight:** 11 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** PO-Oral<br>**Was the product used ok?:** Yes | 25-Jun-2009 | 28-Jun-2018 | 3 Day(s) | D-D | Suspected Adverse Event: On 29 June 2018, the owner reported the following event for Trinka, a 9 year old, 11 pound, spayed female Schnauzer (miniature).<br>25 June 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (M63809AX) was topically applied per label to the dog.<br>28 June 2018: The dog has fleas and developed abrasions underneath her front leg and in axilla on the left side. The owner have the dog on an unknown antibiotic.<br>The dog has not been seen by the vet. The dog has been on FL all her life with no issues. No further medical information available. |
| 29-Jun-2018 | UAE; 18US040956; TN; U.S.A | **Species:** Canine<br>**Breed:** Yorkshire Terrier<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 5.00 Year(s)<br>**Weight:** 12 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 01-Jun-2013* | 26-Jun-2018 | 1 Day(s) | D-D | Suspected Adverse Event: On 29 Jun 2018, the owner reported the following event for Jo Jo Dancer, 5 year old, 12 pound, intact male, Yorkshire Terrier canine.<br>25 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P60712) was applied between the shoulder blades.<br>26 Jun 2018: The pet experienced hair loss through out the body. The pet was not presented to the clinic and no treatment was provided.<br>29 Jun 2018: Symptoms are still ongoing.<br>The pet has received the product since 1 Jun 2013* and no symptoms presented. There is one other dog in the household that also received the product (see case 18US040864). No further medical information is expected. |
| 29-Jun-2018 | UAE; 18US040976; WV; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 13.00 Year(s)<br>**Weight:** 6 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 12-May-2018 | 11-Jun-2018 | 2 Day(s) | D-D | Suspected Adverse Event: On 29 Jun 2018, the owner reported the following event for a Domestic Shorthair Feline (all other signalments unknown).<br>12 May 2018:One vial of FRONTLINE PLUS CATS (R41206AW) was applied between the shoulder blades.<br>9 Jun 2018: Another vial was applied.<br>Unknown date: The pet lost 2 large patches of fur. It is unknown if the pet was presented to the clinic or if any treatment was provided. The status of the pet is unknown.<br>No further medical information is expected.<br>UPDATE 2 Jul 2018 NH: Owner called to report Jojo, 13 year old, 6 pound, neutered male, Domestic Shorthair Feline.<br>11 Jun 2018: The pet experienced intense itching and hair loss on the top of head as well as under the chin. The pet was presented to the clinic. The attending veterinarian adminstered steroid injection and subcutaneous fluids. The veterinarian also prescribed an unknown antibiotic.<br>2 Jul 2018: The pet recovered.<br>No further medical information is expected. |
| 29-Jun-2018 | UAE; 18US041017; MD; U.S.A | **Species:** Canine<br>**Breed:** Pug<br>**Sex:** U | 2 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 23-May-2018* | 30-May-2018* | 1 Week(s) | D-D | Suspected Adverse Event: On 29 Jun 2018, the owner reported the following event for Rosto, a Pug (all other signalments unknown). |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | | | | | 23 May 2018: An unknown amount of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was given to the dog topically (unknown site of application), by the owner. It is unknown if this was the first dose applied. On an unknown date after the application the dog had little red bumps in an unknown location on the body.<br>It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected. |
| 29-Jun-2018 | UAE; 18US041090; IL; U.S.A | **Species:** Canine<br>**Breed:** West Highland White<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 4.00 Year(s)<br>**Weight:** 16 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 29-Jun-2014* | 29-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 29 Jun 2018, the owner reported the following event for Lily, 4 year old, 16 pound, spayed female, Western Highland Terrier canine.<br>29 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied between the shoulder blades. The pet walked outside and the fur on at the application site turned red. The pet was not presented to the clinic and no treatment was provided. After a few minutes the color started to slowly fade but is still present.<br>The pet has received the product since 29 Jun 2014* and no symptoms presented. There is one other dog in the household that also received the product and experienced symptoms (see case 18US041097) No further medical information is expected. |
| 29-Jun-2018 | UAE; 18US041095; MN; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 6.00 Year(s)<br>**Weight:** 15 lbs | 4 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 15-May-2016* | 15-May-2018* | 0 Day(s) | D-D | Suspected Adverse Event: On 29 Jun 2018, the owner reported the following event for Rabbit, a 6 year old, 15 pound, spayed female, Domestic Shorthair (Crossbreed).<br>2016*: The cat started on 1 vial of FRONTLINE PLUS CATS (P41003AW) was given to the cat topically between the shoulder blades, by the owner. The cat was treated monthly on a seasonal basis from May-Nov.<br>15 May 2018*: The cat was given another dose of the product.<br>15 May 2018*: The cat started losing fur at the application site.<br>13 Jun 2018*: The cat recovered.<br>The cat was seen by a veterinarian but was not given any treatment. The cat has had symptoms of lethargy after receiving an unknown vaccine. No further medical information expected. |
| 29-Jun-2018 | UAE; 18US041097; IL; U.S.A | **Species:** Canine<br>**Breed:** Spaniel (Cocker)<br>**Sex:** F<br>**Sex qualifier:** Neutered<br>**Age:** 7.00 Year(s)<br>**Weight:** 11 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 29-Jun-2014* | 29-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 29 Jun 2018, the owner reported the following event for Willow, 7 year old, 11 pound, spayed female, Cocker Spaniel mix canine.<br>29 Jun 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was applied between the shoulder blades. The pet walked outside and the fur on at the application site turned red. The pet was not presented to the clinic and no treatment was provided. After a few minutes the color started to slowly fade but is still present.<br>The pet has received the product since 29 Jun 2014* and no symptoms presented. There is one other dog in the household that also received the product and experienced symptoms (see case 18US041090) No further medical information is expected. |
| 29-Jun-2018 | UAE; 18US041102; CA; U.S.A | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** M<br>**Sex qualifier:** -<br>**Age:** 3.00 Year(s) | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON | 23-Jun-2018 | 23-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 29 Jun 2018, the owner reported the following event for Puper, 3 year old, 33 pound, intact male, Chihuahua mix canine.<br>23 Jun 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (R60516BL) was applied between the shoulder blades. The pet |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **Weight:** 33 lbs | | | | **Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | | | | | experienced intense itching. The pet was not presented to the clinic and no treatment wa provided.<br>29 Jun 2018: Symptoms sre still ongoing.<br>The pet has received the product monthly since 23 Jun 2017 and no symptoms presented.There is one other dog in the household that also received the product and experienced symptoms (see case 18US042008). No further medical information is expected. |
| 29-Jun-2018 | UAE; 18US041148; WI; U.S.A | **Species:** Canine<br>**Breed:** Canine (unknown)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** Unknown to Company | 29-Jun-2018* | 29-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 29 June 2018, the owner reported the following event for a dog of unknown signalment.<br>*29 June 2018" One vial of FRONTLINE PLUS DOG (lot unsubstantiated) (lot unknown). Following the treatment the dog was lethargic.<br>Owner declined the report. |
| 29-Jun-2018 | UAE; 18US041476; LA; U.S.A | **Species:** Feline<br>**Breed:** Domestic Shorthair (Crossbreed)<br>**Sex:** U<br>**Sex qualifier:** Unknown<br>**Age:** 10.00 Week(s)<br>**Weight:** Unknown | 2 | 2 | 0 | **Product used:** FIPRONIL SPRAY<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Unknown to Company | 29-Jun-2018 | 29-Jun-2018 | 0 Day(s) | D-B | Suspected Adverse Event: On 29 Jun 2018, the following event was reported to Safety Call International (SCI) by the veterinarian for two 10 week old Domestic Shorthair, with all other signalments unknown.<br>29 Jun 2018: The cats were applied an unknown amount of FRONTLINE SPRAY (653311) rubbed over their fur due to fleas present. Instantly the kittens began tremoring, fell to their sides, and was borderline unresponsive. Their third eyelids are elevated and one is mydriatic bilaterally. Heart rate approximately 250 and respiratory rate approximately 50 for both kittens. They did not have an intact swallowing reflex. The veterinarian bathed the kittens with Dawn detergent and blow dried them. The kittens were given Karo syrup and lactated ringers SQ. A blood glucose was checked (post Karo syrup) and was 593 and 371. The kittens' temperatures dropped and they were started on supportive heat. The kittens' condition continued to decompensate during the course of the call. They remained non responsive and laterally recumbant. Their temperatures continued to drop. One of the kittens appeared to be agonally breathing at one point. A fecal smear did not show coccidia or other parasites.<br>No further information at this time. |
| 29-Jun-2018 | UAE; 18US042008; CA; U.S.A | **Species:** Canine<br>**Breed:** Chihuahua<br>**Sex:** M<br>**Sex qualifier:** Neutered<br>**Age:** 3.00 Year(s)<br>**Weight:** 30 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** Yes | 23-Jun-2017 | 23-Jun-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 29 Jun 2018, the owner reported the following event for Bear, 3 year old, 30 pound, neutered male, Chihuahua mix canine.<br>23 Jun 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (R60516BL) was applied between the shoulder blades. The pet experienced intense itching. The pet was not presented to the clinic and no treatment wa provided.<br>29 Jun 2018: Symptoms sre still ongoing.<br>The pet has received the product monthly since 23 Jun 2017 and no symptoms presented.There is one other dog in the household that also received the product and experienced symptoms (see case 18US041102). No further medical information is expected. |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 28-Jun-2018 | UAE; 18US042318; NY; U.S.A | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** F **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 4 lbs | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 01-Feb-2018* | 01-May-2018 | 0 Day(s) | D-D | Suspected Adverse Event: On 28 Jun 2018, the owner reported the following event for Mitch, 1 year old, 4 pound, spayed female, Domestic Shorthair feline.<br>1 May 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. The cat ran away and hid for 15 minutes. The pet experienced hypersalivation. The pets were not presented to the clinic and no treatment was provided. The pet recovered after 15 minutes.<br>The pet received the product since 1 Feb 2018 and not symptoms presented. There is 1 other cat in the household that also experienced symptoms (see case 17US086846). No further medical information is expected. |
| 25-May-2018 | UAE; 18UY000006; -; Uruguay | **Species:** Feline **Breed:** Domestic Shorthair (Crossbreed) **Sex:** M **Sex qualifier:** Neutered **Age:** 1.00 Year(s) **Weight:** 3.5 - 4 kg* | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 16-May-2018 | 16-May-2018 | 0 Day(s) | D-D | As reported by the vet who attend a pet owner claim after using FRONTLINE PLUS cat.<br>Toma, male cat, 1 year old, neutered, 3,5-4 kg weight approximately, healthy, received (16/5/18) one pipette of Frontline Plus cat topically above the neck, approximately 2 hours lately, the pet started scratching the application site, the owner observed irritation, erythema, exudation, hair loss, at the application site. These symptom lasted less than 24 hrs, however, scratches injuries are still healing.<br>Toma is a healthy cat, there was not other injuries in his body, mouth, etc.<br>This was the first time Toma received Frontline Plus cat, there was not reaction with other drugs in the past.<br>Toma has a brother who has a similar reaction with Frontline Plus cat, but his injuries were mild and self limiting. |
| 11-Apr-2018 | UAE; 18ZA000052; -; South Africa | **Species:** Feline **Breed:** Domestic Mediumhair (Crossbred) **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 25-Mar-2016* | 26-Mar-2018 | 1 Day(s) | D-E | Suspected Lack Of Efficacy: As reported by the owner, Olive, a cat, female , domestic breed, 2 years old, weight unknown (small), in good health condition, had received FRONTLINE PLUS CAT, administred by topical route by the owner, dosage as per indication by weight, the 25 Mar 2018. The reason of the treatment was parasite control. The cat lives with dogs who are treated with FRONTLINE too. The cat have been treated monthly for 2 years with the product. She is in-house and never had any problem with fleas. The 26 Mar 2018, the cat had fleas. The 11 Apr 2018, the owner sees that the cat still has fleas, and sees the flea dirt as well on cat. The owner used a tablet that is not yet available in South Africa for cats. The reaction is ongoing but the situation is better. |
| 26-Apr-2018 | UAE; 18ZA000059; -; South Africa | **Species:** Canine **Breed:** Pit Bull **Sex:** F **Sex qualifier:** - **Age:** 8.00 Week(s) **Weight:** 5 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | N/A | 25-Apr-2018 | 2 Day(s) | D-D | Suspected Lack of Efficacy: as reported by the attending Vet, a female pitbull dog, 8 weeks, 5 kg, in good health condition, was treated with FRONTLINE PLUS DOG S topically by the owner on 23 Apr 2018, once off. 2 Days after treatment, the owner saw fleas on the puppy and ticks climbing on. It is a house dog. It was the first time the animal was treated with this product. No further information available. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 24-May-2018 | UAE; 18ZA000075; -; South Africa | **Species:** Canine **Breed:** Beagle **Sex:** F **Sex qualifier:** Unknown **Age:** 2.00 Year(s) **Weight:** 10 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 22-May-2018 | 22-May-2018 | 0 Day(s) | D-D | Suspected Adverse Reaction: As reported by the owner, a dog, Beagle, female, 2 years old, 10 kg, in a good health condition prior treatement received FRONTLINE PLUS DOG M (BN P62003A, exp date Aug 2019) , on topical route, 1.34 ml, administered by the owner for parasite control on 22 May 2018. 20 minutes after the administration, the dog experienced difficulty jumping on couch. She walked very slow, looked like her lower back was in pain. Owners bathed her in order to get the Frontline off, she still walks slowly and cannot sit or jump.The reaction was treated with Petcalm for 3 days. The dog is a little better but the reaction is still ongoing. The dog previously received FRONTLINE PLUS M without any reaction. The owners thought she might have hurt her back but then they realized that it was severe side effect from the Fipronil and want to know how long side effect will last. |
| 26-Jun-2018 | UAE; 18ZA000081; -; South Africa | **Species:** Canine **Breed:** French Bulldog **Sex:** F **Sex qualifier:** Unknown **Age:** 5.00 Year(s) **Weight:** 12 kg | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** Yes | 23-Jun-2018 | 23-Jun-2018 | 0 Day(s) | D-D | Suspected Advert Event report: as reported by owner, a female dog, Libby, French Bulldog, 5 years old, 12 kg weight, in good health condition received FRONTLINE PLUS DOG 10-20kg (BN and exp date unknown) administered topically by owner on 23 June 2018. On the same evening, the dog experienced a chemical burn on the neck where the product was applied. Hair is falling away and skin inflamed. Raw sore now oozing and bleeding. The reaction was not treated. The reaction is ongoing. This is the extent of information available. |

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* Indicates Approximate date or weight

# Worldwide Adverse Event Reports Involving - Human Cases
## Reporting Period: 01-Apr-2018 to 01-Jul-2018 [1]

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 25-Jun-2018 | UHAE; 18BR004362; ES; Brazil | **Sex:** F **Sex qualifier:** -**Age:** 7.00 Year(s) **Weight:** 22.5 Kilograms | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Off label use / Indication) | 22-Jun-2018 | 23-Jun-2018 | 1 Day(s) | H-D | Suspected Adverse Event: AS reported by the victim's godfather, a 7-year-old, 22.5 kg, female child, was playing with two rescued cats treated with FRONTLINE SPRAY (FL) (lot and exp unknown), applied topically, location unknown, by the reporter, on 22 Jun 2018, for unknown reason. One day later (23 Jun 2018), the child experienced blistering on whole body. Loratadine and topical anti-allergy medication used for treatment, with no improvement. Yesterday (24 Jun 2018) the child was taken to a hospital and cefalexine was prescribed. The signs are still ongoing. There is no further information available. UPDATE 28 JUN 2018 - The child was taken to the clinic and she has chickenpox. She remains under treatment (details not provided). There is no further information expected. |
| 24-Apr-2018 | UHAE; 18DE000307; -; Germany | **Sex:** M **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPRAY **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure) | 18-Apr-2018 | 19-Apr-2018* | 12 hours | H-D | symptomatic human exposure: the animal owner reported, that he treated his animals with FRONTLINE SPRAY on 18 Apr 2018. Accidently he sprayed himself (unknown where exactly) and he stepped on the bottle and so the feet got on contact with the product, too. About 12 hours later there was reddening and pruritus of the affected skin. The symptoms were decreasing after taking a daily shower, and there was no longer pruritus at the day reporting (25 Apr 2018). |
| 15-May-2018 | UHAE; 18DE000368; -; Germany | **Sex:** F **Sex qualifier:** Unknown**Age:** 59.00 Year(s) **Weight:** 67 Kilograms | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON CAT **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure) | 15-May-2018 | 15-May-2018 | directly | H-D | symptomatic human exposure: a female animal owner (59 years old, 67 kg body weight) was treating her cat with FRONTLINE SPOT ON K for parasite control on 15 May 2018. She did´t notice that she had a small wound on her thumb, and when getting in contact with the product accidentally she felt a burn in the wound for only a few seconds. No other details. |
| 06-Jun-2018 | UHAE; 18FR000730; -; France | **Sex:** F **Sex qualifier:** -**Age:** 7.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL SPOT ON DOG **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure) | 20-Mar-2018* | 20-Apr-2018 | 31 Day(s) | H-D | FR-ANMV-18 CPVL 00850: A school teacher noticed that a child was bearing lice. She had dry and damaged hair and also hair loss. In history: she had been applied preceding month with FRONTLINE SPOT ON CHIEN by her mother. Time to onset/duration of signs is not known. Outcome of SAR: Unknown. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 09-Apr-2018 | UHAE; 18SE000050; -; Sweden | **Sex:** F **Sex qualifier:** Pregnant**Age:** 26.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Off label use / Indication) | 06-Apr-2018 | 06-Apr-2018 | 0 Day(s) | H-D | The owner treated her cat (7 months old domestic shorthair male cat, 2.7 kg) with Frontline Comp spot-on, batch no unknown, topical in the neck. 1 hour later the owner kissed the cat in the neck, inhaled the substance and got it on the lips. Directly after exposure she washed hands, lips and brushed her teeth. Now it stings a little in the mouth and it is a little numb, but not too much. She is pregnant in week 6. |
| 02-Apr-2018 | UHAE; 18US017164; NC; U.S.A | **Sex:** F **Sex qualifier:** Unknown**Age:** 41.00 Year(s) **Weight:** 95.000 Pounds | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure) | 02-Apr-2018* | 02-Apr-2018 | 0 Day(s) | H-D | Human Exposure: On 2 Apr 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 41 year old, 95 pound, female of further unknown signalment.<br>2 Apr 2018: When the patient was opening a vial of FRONTLINE PLUS DOG 5-22 LBS (P60152AL), some of the product splashed on her face and in her right eye, resulting in ocular irritation, pain, redness and conjunctivitis. The patient subsequently irrigated her eye with water, followed by saline.<br>The reporter's current status cannot be confirmed; however, she was not wearing contacts at the time of product exposure. She does have a history of experiencing seasonal allergies, osteoporosis and rheumatoid arthritis.<br>UPDATE 4 Apr 2018 - SCI attempted follow up with patient on 3 Apr 2018. No answer, left message requesting follow up.<br>UPDATE 5 Apr 2018 - SCI attempted follow up with patient on 4 Apr 2018. No answer, left message requesting follow up.<br>UPDATE 6 Apr 2018 - SCI attempted follow up with patient on 5 Apr 2018. No answer, left message requesting follow up.<br>No further medical information expected. |
| 27-Apr-2018 | UHAE; 18US024297; NC; U.S.A | **Sex:** F **Sex qualifier:** Unknown**Age:** 22.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure) | 27-Apr-2018 | 27-Apr-2018 | N/A | H-E | Human Exposure: On 4 Apr 2018, the following inquiry was reported to Safety Call International (SCI) by the clinic staff for FRONTLINE PLUS DOG 45-88 LBS (R60206AR).<br>Product was applied to dog this morning. About 45 minutes ago patient was playing with the dog and kissed the dog at the application site. She washed and has been asymptomatic. Caller would like to know of any poisoning concerns. |
| 27-Apr-2018 | UHAE; 18US024318; -; U.S.A | **Sex:** F **Sex qualifier:** Unknown**Age:** - **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products | 27-Apr-2018 | 27-Apr-2018 | N/A | H-E | Human Exposure: On 30 Apr 2018, the following inquiry was reported to Safety Call International (SCI) by the pet owner for FRONTLINE PLUS (product unsubstantiated) (lot unknown).<br>Caller accidentally got product on her skin 1 hour ago. She washed thoroughly and has been asymptomatic. Caller would like to know of any poisoning concerns. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure) | | | | | |
| 30-Apr-2018 | UHAE; 18US024520; -; U.S.A | **Sex:** F **Sex qualifier:** Unknown**Age:** 42.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Off label use / Indication) | 28-Apr-2018 | 28-Apr-2018 | N/A | H-E | Human Exposure: On 28 Apr 2018, the following inquiry was reported to Safety Call International (SCI) by the pet owner for FRONTLINE PLUS DOG 5-22 LBS (R61421AL).<br>28 Apr 2018: Caller states her husband applied the product to the dog this morning but did not tell he. About five minutes prior to the call she picked up the dog and gave it a kiss. She must have gotten some product residue on her lips, there was nothing wet but she has the smell of the product and can taste the product. She is concerned about the exposure. Caller declined to provide her address.<br>UPDATE 3 May 2018 - SCI attempted follow up with patient on 2 May 2018. No answer, left message requesting update.<br>UPDATE 4 May 2018 - SCi attempted follow up with patient on 3 May 2018. No answer, left message requesting update.<br>UPDATE 7 May 2018 - SCI attempted follow up with patient on 4 May 2018. No answer, left message requesting update. Final attempt.<br>No further information is expected. |
| 01-May-2018 | UHAE; 18US025129; -; U.S.A | **Sex:** F **Sex qualifier:** Unknown**Age:** 78.00 Year(s) **Weight:** 138 Pounds | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure) | 01-May-2018* | 01-May-2018 | N/A | H-E | Human Exposure: On 1 May 2018, the following inquiry was reported to Safety Call International (SCI) by the pet owner for FRONTLINE PLUS DOG 89-132 LBS (R360608A).<br>Caller states she snapped the cap off product and some of the product went into her left eye. She immediately used eye drops and she is asymptomatic. She does not wear contact lenses.<br>UPDATE 3 May 2018 - SCI attempted follow up with patient on 2 May 2018. No answer, left message requesting update.<br>UPDATE 4 May 2018 - SCI attempted follow up with patient on 3 May 2018. No answer, left message requesting update.<br>UPDATE 7 May 2018 - SCI attempted follow up with patient on 4 May 2018. No answer, left message requesting update. Final attempt.<br>No further medical information expected. |
| 07-May-2018 | UHAE; 18US026340; KY; U.S.A | **Sex:** M **Sex qualifier:** -**Age:** 12.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure) | 05-May-2018* | 05-May-2018 | N/A | H-E | Human Exposure: The following human exposure was reported by a relative to Safety Call International (SCI) for a 12 year old, male patient of further unknown signalment.<br>5 May 2018: A family member applied a dose of FRONTLINE PLUS DOG 89-132 LBS (96310AR) (Lot Invalid) topically to their dog. Later that day, the child may have touched the application site. The child is asymptomatic and acting like his usual self, and did briefly wash his hands after exposure.<br>No further medical information expected. |
| 07-May-2018 | UHAE; 18US026376; NY; U.S.A | **Sex:** F **Sex qualifier:** Unknown**Age:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 07-May-2018* | 07-May-2018 | 0 Day(s) | H-D | Human Exposure: On 7 May 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 24 year old, 125 pound, female of further unknown signalment. |

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Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 24.00 Year(s)<br>**Weight:** 125 Pounds | | | | METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Human exposure) | | | | | 7 May 2018: While applying FRONTLINE PLUS CATS (P41104AW) to her cat, some of the product got onto the patient's index finger (left hand). Between 3-5 minutes following skin contact, her finger began tingling prompting her to wash her hands thoroughly.<br>To date, it's unknown if the reported paraesthesia continues. No further medical information expected. |
| 08-May-2018 | UHAE; 18US026730; MN; U.S.A | **Sex:** M<br>**Sex qualifier:** Unknown**Age:** 32.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Ophthalmic<br>**Was the product used ok?:** No (Human exposure) | 08-May-2018 | 08-May-2018 | 0 Day(s) | H-D | Human Exposure: On 8 May 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 32 year old, male, of further unknown signalment.<br>8 May 2018: After applying unknown FRONTLINE (lot unknown) (product unsubstantiated) to his dog, the patient accidentally laid on the dog and suspects some of the product got into his eye (OS). He was not wearing contact lenses at the time of exposure, but did experience ocular irritation. He subsequently irrigated his eye for two minutes, though his current status is unknown.<br>No further medical information expected.<br>UPDATE 9 May 2018: SCI contacted the patient for update. Patient rinsed eye for several minutes, and symptoms resolved within an hour. |
| 10-May-2018 | UHAE; 18US027189; NY; U.S.A | **Sex:** F<br>**Sex qualifier:** Unknown**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Human exposure) | 10-May-2018* | 10-May-2018 | 0 Day(s) | H-D | Human Exposure: On 10 May 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, an adult, female of further unknown signalment.<br>10 May 2018: The patient got an unknown amount of FRONTLINE PLUS DOG 5-22 LBS (M62901AL) on her hands while applying the product to her dog. Immediately following product exposure, she noticed a tingling sensation on her fingers, but washed her hands for a couple of minutes. After washing the exposed skin, she recovered.<br>The patient has a history of high cholesterol. No further medical information expected. |
| 10-May-2018 | UHAE; 18US027289; GA; U.S.A | **Sex:** F<br>**Sex qualifier:** -**Age:** 32.00 Year(s)<br>**Weight:** 130 Pounds | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Ophthalmic<br>**Was the product used ok?:** No (Human exposure) | 10-May-2018* | 10-May-2018 | 0 Day(s) | H-D | Human Exposure: On 10 May 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 32 year old, 130 pound, female of further unknown signalment.<br>10 May 2018: While applying FRONTLINE PLUS DOG 45-88 LBS (R60601BR), some of the product splashed and got into her left eye (OS), causing a burning sensation. The patient subsequently irrigated the OS with water after which, the burning stopped. There was also some ocular irritation, but that has also subsided.<br>No further medical information expected. |
| 14-May-2018 | UHAE; 18US028771; | **Sex:** F<br>**Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL | 13-May-2018 | 14-May-2018 | N/A | H-E | Human Exposure: On 14 May 2018, the following event was reported to Safety Call International (SCI) by the patient, a 56 year |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | CA; U.S.A | -**Age:** 56.00 Year(s) **Weight:** 185.000 Pounds | | | | 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** PO-Oral **Was the product used ok?:** No (Human exposure) | | | | | old, 185 pound, female, with other unknown signalment.<br>14 May 2018: Approximately 30 minutes prior to report, patient used a knife to open the FRONTLINE PLUS DOG 45-88 LBS (lot unknown). The same knife was then used to cut up her food forgetting that she had used that knife. Patient is unsure if the knife had any of the product on it. She states she only had two bites of the food when she realized what she had done. Patient is asymptomatic at this time.<br>No further information is expected. |
| 15-May-2018 | UHAE; 18US028972; -; U.S.A | **Sex:** F **Sex qualifier:** Unknown**Age:** 40.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure) | 15-May-2018* | 15-May-2018 | 0 Day(s) | H-D | Human Exposure: On 14 May 2018, the following event was reported to Safety Call International (SCI) by the family member for a 40 year old, female, with other unknown signalment.<br>15 May 2018: Caller states that his wife got a small amount of the FRONTLINE PLUS DOG 5-22 LBS (lot unknown) on her finger about 20 minutes ago. She washed her hands for 17 minutes. She has a funny taste in her mouth. She did not get the product in her mouth.<br>No further information is expected. |
| 15-May-2018 | UHAE; 18US028993; -; U.S.A | **Sex:** F **Sex qualifier:** Unknown**Age:** 26.00 Year(s) **Weight:** 250.000 Pounds | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure) | 15-May-2018* | 15-May-2018 | N/A | H-E | Human Exposure: On 14 May 2018, the following event was reported to Safety Call International (SCI) by patient, a 29 year old, 250 pound, female, with other unknown signalment.<br>15 May 2018: Patient was putting FRONTLINE PLUS CAT (R40202BW) on her cat approximately 5-10 minutes ago. The package opened and the product got on her right hand. She washed her hand right away and is asymptomatic at this time.<br>No further information is expected. |
| 16-May-2018 | UHAE; 18US029261; MO; U.S.A | **Sex:** F **Sex qualifier:** Lactating**Age:** 36.00 Year(s) **Weight:** 150 Pounds | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure) | 16-May-2018* | 16-May-2018 | 0 Day(s) | H-D | Human Exposure: On 16 May 2018, the following human exposure was reported to Safety Call International (SCI) by the pet owner, a female of unknown signalment.<br>16 May 2018: The pet owner applied an unknown dose of FRONTLINE PLUS DOG 45-88 LBS (R60601BR) to her dog when some of the product got on her finger. She immediately washed her hand for 5 minutes. After washing, her hand and finger felt dry.<br>UPDATE 23 May 2018 - SCI followed up with patient on 22 May 2018. Patient reports she washed her hands as advised and applied skin moisturizer. Symptoms resolved within a few minutes after applying skin moisturizer.<br>No further medical information expected. |
| 18-May-2018 | UHAE; 18US029685; | **Sex:** F **Sex qualifier:** | 1 | 1 | 0 | **Product used:** FIPRONIL | 18-May-2018 | 18-May-2018 | 0 Day(s) | H-D | Human Exposure: On 18 May 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 36 |

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* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | CA; U.S.A | Unknown**Age:** 36.00 Year(s) **Weight:** Unknown | | | | 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure) | | | | | year old, female of further unknown signalment.<br>18 May 2018: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (M63306AL) got into her eye. The patient experienced burning and irritation in the eye, but upon rinsing her eye with an unknown liquid, she recovered.<br>No further medical information expected. |
| 21-May-2018 | UHAE; 18US030160; WI; U.S.A | **Sex:** F **Sex qualifier:** Unknown**Age:** 30.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Ophthalmic **Was the product used ok?:** No (Human exposure) | 19-May-2018* | 19-May-2018 | 0 Day(s) | H-D | Human Exposure: On 21 May 2018, the following human exposure was reported to Safety Call International (SCI) by the pet owner, a 30 year old female, other signalment unknown.<br>19 May 2018: The pet owner was applying a dose of FRONTLINE PLUS DOG 5-22 LBS (Lot Unknown) to her dog when a small, unknown amount of product contacted her eye. An unknown amount of time later, her eye became red and hurt. She rinsed her eye and applied a cold compress. Her symptoms resolved.<br>UPDATE 22 May 2018 - SCI attempted follow up on 21 May 2018. No answer, left message requesting follow up.<br>UPDATE 23 May 2018 - SCI followed up with patient on 22 May 2018. Patient reports that she rinsed eyes as instructed and symptoms resolved within 1 hour. Caller had to disconnect before collecting any further details.<br>No further medical information expected. |
| 22-May-2018 | UHAE; 18US030276; MN; U.S.A | **Sex:** F **Sex qualifier:** -**Age:** 64.00 Year(s) **Weight:** 172 Pounds | 1 | 0 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other products **Route:** Topical / Cutaneous **Was the product used ok?:** No (Human exposure) | 21-May-2018* | N/A | N/A | H-E | Human Exposure: On 21 May 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 64 year old, 172 pound, female of further unknown signalment.<br>21 May 2018: The patient got an unknown amount of unknown FRONTLINE (RM113301; invalid lot) (product unsubstantiated) on her skin after she touched her dog post product application. She has since rinsed her hand with water and remains asymptomatic. The reporter has an unknown congenital heart condition and is allergic to sulfa, ciprofloxacin, Macrobid, Macrodantin, ragweed and dust. The reported product is marked as unsubstantiated because it was originally listed as FRONTLINE PLUS DOG 5-22 LBS (by the VTS technician who transferred the patient to SCI), but was reported by SCI as FRONTLINE GOLD DOG 5-22 LBS. Moreover, the reported lot number, although it's invalid, is more consistent with FRONTLINE PLUS and not FRONTLINE GOLD.<br>No further medical information expected.<br>UPDATE 22 May 2018: SCI attempted to follow up with the patient, but was unsuccessful. A message was left requesting a callback.<br>No further medical information expected.<br>UPDATE 24 May 2018 - SCI followed up with patient on 23 May 2018. Caller washed area and remained asymptomatic.<br>No further medical information expected. |
| 21-May-2018 | UHAE; 18US030590; NY; U.S.A | **Sex:** F **Sex qualifier:** Unknown**Age:** 58.00 Year(s) **Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON **Other products used:** no other | 21-May-2018* | 21-May-2018 | 0 Day(s) | H-D | Human Exposure: On 21 May 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 58 year old, female, of further unknown signalment.<br>21 May 2018: While trying to open a vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown), the patient got the product on her lip and tongue. Presently, she is unable to get the poor taste out of her mouth and her lips feel numb. |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Human exposure) | | | | | UPDATE 23 May 2018 - SCI attempted follow up with patient on 22 May 2018. No answer, left message requesting follow up.<br>UPDATE 24 May 2018 - SCI followed up with patient on 23 May 2018. Patient indicated that symptoms resolved within 1 hour. Patient disconnected call before any further information could be obtained.<br>The patient is a smoker. No further medical information expected. |
| 23-May-2018 | UHAE; 18US031234; -; U.S.A | **Sex:** F<br>**Sex qualifier:** Lactating**Age:** 32.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Human exposure) | 23-May-2018 | 23-May-2018 | N/A | H-E | Human Exposure: On 23 May 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 32 year old, lactating female patient of further unknown signalment.<br>On 23 May 2018: The patient nipped open the tube of FRONTLINE PLUS DOG 23-44 LBS (P61322AL) and got some product on her hands. She washed with soap and water and is asymptomatic. She's concerned because she breast feeding her 9 month old. She also states there was a tick embedded in the dog and when she tried to remove it, it broke and some stayed in the dog. She put the product on that area and wants to know if it will kill the tick or if there is cause for concern. Caller declined address.<br>No further information is expected. |
| 04-Jun-2018 | UHAE; 18US034013; MA; U.S.A | **Sex:** M<br>**Sex qualifier:** -**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** - | 04-Jun-2018* | 04-Jun-2018 | N/A | H-E | Human Exposure: On 4 Jun 2018, the following human exposure was reported by the pet owner to Safety Call International (SCI) for a male patient of further unknown signalment.<br>4 Jun 2018: The patient was putting the FRONTLINE PLUS DOG 5- 22 LBS (R61709BL) on his dog and accidentally spilled some on his hand, approximately 30 minutes prior to the report. Patient ran water over it for approximately 15 minutes. Patient is asymptomatic at this time. Patient is unwilling to provide his medical history and address.<br>No further information is expected.<br>UPDATE 5 Jun 2016: SCI contacted the patient for follow up. Left message for patient to callback with any concerns. No further information is expected.<br>UPDATE 7 Jun 2016: SCI contacted the patient for follow up on multiple attmepts. To date the information has been received by SCI.<br>UPDATE 8 Jun 2018 - SCI attempted follow up with patient on 7 Jun 2018. Line was repeatedly answered and disconnected, unable to leave a message.<br>No further information is expected. |
| 01-Jun-2018 | UHAE; 18US034087; TN; U.S.A | **Sex:** F<br>**Sex qualifier:** Unknown**Age:** 46.00 Year(s)<br>**Weight:** 300 Pounds | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** PO-Oral<br>**Was the product used ok?:** No (Human exposure) | 01-Jun-2018* | 01-Jun-2018 | 0 Day(s) | H-D | Human Exposure: On 1 Jun 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 47 year old, 300 pound, non-pregnant, female of further unknown signalment.<br>1 Jun 2018: The patient got an unknown amount of FRONTLINE PLUS CATS (R41105AW) on her hands and though she doesn't recall touching her mouth following product exposure, she suspects she ingested some of it because she has a bad taste in her mouth and is spitting frequently. It was confirmed that she is not experiencing any difficulty breathing or swallowing. The patient has since washed her hands and sipped on unknown fluids.<br>The patient's current status is unknown and she is known to be allergic to penicillin and Codeine. No further medical information expected.<br>UPDATE 5 Jun 2018: Per the e-mail received, SCI attempted to |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | | | | | | | | | | call back the patient, but there was no answer and a voice mail box was not set up, so a message could not be left.<br>UPDATE 7 Jun 2018 - SCI followed up with patient on 6 Jun 2018. Patient rinsed mouth and brushed her teeth. Symptoms resolved within approximately 2 hours.<br>No futher medical information expected. |
| 03-Jun-2018 | UHAE; 18US034151; PA; U.S.A | **Sex:** F<br>**Sex qualifier:** Unknown**Age:** 54.00 Year(s)<br>**Weight:** 110 Pounds | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Human exposure) | 01-Jun-2018* | 03-Jun-2018* | 2 Day(s) | H-D | Human Exposure: On 3 Jun 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 54 year old, 110 pound, non-pregnant, female of further unknown signalment.<br>1 Jun 2018: The patient initially reported to SCI that she was scratched on her wrist by one of her cats while trying to put the cat in a carrier so the feline could be taken to the veterinary clinic. Conversely, the patient later stated that the scratch was inflicted from her holding the cat while applying FRONTLINE PLUS CATS (R401108W) (invalid lot) to said feline.<br>3 Jun 2018: The patient is now observing a red line going up her arm (unknown side), presumably from where she was originally scratched.<br>At this time, no therapies have been administered for the ongoing dermatological symptoms. The patient also reported that she is a smoker and is allergic to everything outside. An inquiry with product questions was also saved. Please see case 18US034207.<br>No further medical information expected. |
| 11-Jun-2018 | UHAE; 18US035229; NJ; U.S.A | **Sex:** F<br>**Sex qualifier:** Unknown**Age:** 70.00 Year(s)<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Human exposure) | 08-Jun-2018* | 08-Jun-2018 | N/A | H-E | Human Exposure: On 8 Jun 2018, the following human exposure was reported to Safety Call International (SCI) by the pet owner for herself, a 70 year old female, other signalment unknown.<br>8 Jun 2018: The owner opened a vial of FRONTLINE PLUS DOG 5-22 LBS (Lot Unknown) and got some on her finger. She washed her hand with soap and water and is experiencing no symptoms.<br>No further medical information expected. |
| 13-Jun-2018 | UHAE; 18US036660; AL; U.S.A | **Sex:** F<br>**Sex qualifier:** Unknown**Age:** 59.00 Year(s)<br>**Weight:** 132 Pounds | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Ophthalmic<br>**Was the product used ok?:** No (Human exposure) | 13-Jun-2018* | 13-Jun-2018 | 0 Day(s) | H-D | Human Exposure: On 13 Jun 2018, the following human exposure was reported by a patient to Safety Call International (SCI) for a 59 year old, 132 pound female patient of further unknown signalment.<br>Unknown Date: The dog had a dose of FRONTLINE PLUS DOG (lot unknown) (product unsubstantiated) applied.<br>13 Jun 2018: Owner bathed the dog outside approximately one hour ago. The dog was wet and was shaking water. The water went into her right eye. She immediately grabbed a jug of water that she had outside and rinsed her right eye. She then went inside and rinsed her right eye in the sink for a minute and then rinsed her eye again while in the shower. She reports she rinsed for approximately 5 minutes in total. She states her eye is red and feels really dry, but she knows this can also be from all of the rinsing she has done. No further medical information expected. |
| 25-Jun-2018 | UHAE; 18US039294; KS; U.S.A | **Sex:** F<br>**Sex qualifier:** Unknown**Age:** | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S | 24-Jun-2018* | 24-Jun-2018 | 0 Day(s) | H-D | Human Exposure: On 25 Jun 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 46 year old, 190 pound, non-pregnant, female of further unknown |

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| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
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| | | 46.00 Year(s)<br>**Weight:** 190.000 Pounds | | | | METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** No (Human exposure) | | | | | signalment.<br>24 Jun 2018: The patient was experiencing drainage from her right eye in the morning. Around 12:00 PM, she applied unknown FRONTLINE (lot unknown) (product unsubstantiated) to all five of her dogs. Following application, she washed her hands, but about five hours later, her eye (OD) began watering and hurting slightly around the corner of the lid. Following symptom onset, the patient flushed the affected eye as a precaution and reported to SCI that it is possible that the pain may be due to her rubbing her eye all day.<br>25 Jun 2018: The reporter presented to urgent care for evaluation where the attending physician advised that he or she does not suspect the symptoms are related to her possible FRONTLINE exposure. Conversely, she was advised to begin taking unknown over-the-counter cold medications to treat the symptoms.<br>Presently, the patient's status is unknown. She did state that at the time of product application, she thought she was coming down with a cold and has a history of uveitis (OD), as well as Hashimoto's thyroiditis.<br>UPDATE 2 Jul 2018 - SCI followed up with patient on 29 Jun 2018. Patient provided very brief update but indicated that her doctor believes the symptoms are related to a cold and not to product exposure.<br>No further medical information expected. |
| 24-Jun-2018 | UHAE; 18US039712; HI; U.S.A | **Sex:** F<br>**Sex qualifier:** Unknown**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** No (Off label use / Indication) | 24-Jun-2018* | 24-Jun-2018 | 0 Day(s) | H-D | Human Exposure: On 24 Jun 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a female of further unknown signalment.<br>24 Jun 2018: The patient cut herself trying to get into the outer plastic of the container of FRONTLINE PLUS CATS (lot unknown). The patient did use scissors to get into the packaging, but confirmed that the several cuts sustained on both of her hands were from the plastic, not the scissors.<br>The reporter refused to answer any questions asked by SCI and disconnected the call when her ride arrived to take her to a clinic to be treated. It also could not be confirmed if the plastic container referred to the blister packaging or the vial itself. No further medical information expected.<br>Update 06 Jul 2018: Per lack of information, route of administration and dose were changed to unknown. |
| 24-Jun-2018 | UHAE; 18US039715; OH; U.S.A | **Sex:** M<br>**Sex qualifier:** Unknown**Age:** 65.00 Year(s)<br>**Weight:** 135.000 Pounds | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Human exposure) | 24-Jun-2018* | 24-Jun-2018 | 0 Day(s) | H-D | Human Exposure: On 24 Jun 2018, the following human exposure was reported to Safety Call International (SCI) by the patient, a 65 year old, 135 pound, male of further unknown signalment.<br>24 Jun 2018: The patient got an unknown amount of FRONTLINE PLUS DOG 23-44 LBS (R61201BR) on his hands while applying it to his dog around 8:00 AM. Shortly following product exposure, he washed his hands with Dawn dish detergent, but about six hours later, he began experiencing stomach cramps and an hour after that, experienced onset of diarrhea. An unknown duration following onset, the cramping has since subsided, but the diarrhea remains ongoing.<br>It's unknown if any treatment has been administered; however, the patient does have a history of gastroesophageal reflux disease (GERD). No further medical information expected. |
| 26-Jun-2018 | UHAE; 18US039759; PA; U.S.A | **Sex:** F<br>**Sex qualifier:** Unknown**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE | 26-Jun-2018* | 26-Jun-2018 | 0 Day(s) | H-D | Human Exposure: On 26 Jun 2018, the following human exposure was reported by the patient, a female of further unknown signalment.<br>26 Jun 2018: The patient got an unknown amount of FRONTLINE |

N/A signifies the information for this field is either not available or not applicable

1. Due to system limitations the end date is displayed as 1 July 2018, however only cases with a date first valid from 1 April 2018 through 30 June 2018 are displayed.

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)

* Indicates Approximate date or weight

| Date case Received | Case type; Case Reference; State and Country of Occurrence | Patient | # Treated | # Reacted | # Died | Product(s) | Product Start Date | Date Reaction Started | Time to Onset | EPA Code | Event Narrative |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 9% SPOT ON<br>**Other products used:** no other products<br>**Route:** Topical / Cutaneous<br>**Was the product used ok?:** No (Human exposure) | | | | | PLUS DOG 5-22 LBS (lot unknown) onto her thumb. She has since tried rinsing off the product, but remains painful .<br>It's unclear if the pain sustained was localized or generalized and presently, the reporter's status is unknown. No further medical information expected.<br>UPDATE 3 Jul 2018: Safetycall International (SCI) attempted callback to patient to follow up on status. Left message for patient. To date, the information has not been received by SCI . No further information is expected.<br>UPDATE 5 Jul 2018: SCI attempted callback to patient to follow up on status. Left message for patient. To date, the information has not been received by SCI. No further information is expected.<br>UPDATE 06 Jul 2018 for information received 26 Jun 2018: On 26 Jun 2018, the patient reported the following to Safetycall International (SCI). The FRONTLINE PLUS was being applied to her dog approximately 20 minutes prior to her reporting to SCI on 26 Jun 2018. After applying the product to her dog she stuck her left thumb down into the product that was on her dog. She immediately rinsed the product off. She reports she has a little tingling to her left thumb but wasn't sure if it was being caused by the product or because she was worried. No further information is expected.<br>UPDATE 6 Jul 2018: SCI contacted patient to follow up on status. The tingling lasted for just a few hours. The patient rinsed the exposed area as treatment. The symptoms resolved 26 Jun 2018. No further information is expected. |
| 16-Apr-2018 | UHAE; 18ZA000055; -; South Africa | **Sex:** F<br>**Sex qualifier:** -<br>**Age:** -<br>**Weight:** Unknown | 1 | 1 | 0 | **Product used:** FIPRONIL 10%/S METHOPRENE 12% SPOT ON<br>**Other products used:** no other products<br>**Route:** unknown<br>**Was the product used ok?:** No (Human exposure) | 15-Apr-2018 | 15-Apr-2018 | 0 Day(s) | H-D | Human Exposure Case: As reported by the owner, an adult female (other signalment unknown), she applied topically on her cat FRONTLINE PLUS CAT (BN and exp date unknown) on 15 Apr 2018. The owner who applied the product, kissed the cat after application without thinking of FRONTLINE, on 15 Apr 2018. She reported that she thought some of the Frontline might have gotten into her mouth and about 3 hours she had a strange sensation on her tongue. The tip of her tongue felt numb. She went for a run the next morning on 16 Apr 2018 and said she felt a lack of energy. She ingested a very small amount. There is not more information about the evolution or the potential treatment of the owner. Update 20 Apr 2018: the owner contacted to report that her tongue is still numb but energy level are a bit better. |

N/A signifies the information for this field is either not available or not applicable



1. Due to system limitations the end date is displayed as 1 July 2018, however only cases with a date first valid from 1 April 2018 through 30 June 2018 are displayed.

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population - male(s) and female(s)
* Indicates Approximate date or weight

ED_005739D_00014397-00443

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18AR000042 |
| | Address<br>Zoocios<br>Av. 532 y 2 bis<br>La Plata<br>La Plata, Buenos Aires, Argentina<br>1900, Argentina | | Address<br>--UNKNOWN-- | |
| | Phone # 54-221-6364545 | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 06-25-2018 | Date registrant became aware of incident. 06-28-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 94360 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s) FIPRONIL SPRAY | A.I. (s) | A.I. (s) |
| | Product 1 name FRONTLINE SPRAY | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? No<br>Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Unknown use | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00444

Internal ID # 18AR000042

Brief description of incident circumstances

As reported Dr. Arizaga, name unknown, 50 days, 1 to 2 kg approximately, canine, mixed breed, unknown reproductive status, received FRONTLINE SPRAY x 250 ml, batch unknown, expiry unknown, topical, dose: 15 mg per kg, administered by DVM on 25 June 2018. 20 minutes after product administration the owner took them to the vetererinarian dead. The pappies were found the previous day on the street.

| Demographic information:<br>Age: 50 Day(s) -<br>Sex : Unknown<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>0 Day(s) | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>15 Milligram(s) per 1 animal<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>1 - 2 kg* | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18AR000042

* approximate



ED_005739D_00014397-00445

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Mr LEANDRO UNKNOWN | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18BR003816 |
| | Address<br>Brazil | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>05-12-2018 | Date registrant became aware of incident.<br>05-17-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>4.913/94 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL SPRAY | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE SPRAY | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>Yes<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>In the neck | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00447

Internal ID # 18BR003816

Brief description of incident circumstances

Suspected Adverse Event: Initially as reported by the owner via retail outlet:: Mel, age unknown, 3 to 5 kilogram,canine, female,Shih Tzu, received FRONTLINE SPRAY (FL) (lot 003/17 and exp date unknown, topically, applied in the neck), applied by the owner, on saturday (12 May 2018) around 6 p.m. and on sunday (13 May 2018) around 2 p.m., for flea treatment. According to the owner, on saturday, the animal was taken to the pet shop to receive a bath and cut the hair, by that time, the animal was in a good health state. After the bath, the animal was returned home around 3 to 4 p.m. and during the meal time presented loss of appetite. On sunday the animal was apathetic and by monday presented vomiting, hypersalivation and diarrhea, initially without blood, but later on with blood in vomiting and diarrhea. On tuesday (15 May 2018) the animal presented an intense drooling and died around 11 a.m. Mel gave birth 30 days prior to the incident and her puppy also received FL and had a reaction (see case 18BR003817). It is unknown if the animal already received FL in the past. No further information is available.

ED_005739D_00014397-00448

| Demographic information:<br>Age: Unknown -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms: | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Anorexia<br>Lethargy<br>Haematemesis<br>Haemorrhagic diarrhoea<br>Death<br>Hypersalivation<br>Hypersalivation | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>Unknown per 1 animal<br>Expose duration:<br>1 Day(s)<br>Patient weight:<br>3 - 5 kg | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18BR003816

ED_005739D_00014397-00449

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18CH000037 |
| | Address<br>Switzerland | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 04-07-2018 | Date registrant became aware of incident. 05-17-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>56'044 001 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 12% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE COMBO CATS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation<br>Topicals | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>No<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Unknown use | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00450

Internal ID # 18CH000037

Brief description of incident circumstances

Suspected Adverse Reaction: As reported by the attending vet, a cat, European Shorthair, male neutered, 10 years old, weight unknown, in a good health condition, was treated for prophylaxis, with FRONTLINE COMBO (BN and exp date unknown), dosage unknown, administered topically on an unknown site by the owner, on 7 Apr 2018. 10 minutes after the administration, the cat experienced foam from the mouth and died. The cat has previously received this product but there is no information about the dates of administration and the possible previous reactions. No information is available concerning concomittant administration on the same day of other products. The attending vet level of suspicion is unknown. Update 01 June 2018: necropsy results were provided. The cat is named Schrek, date of necropsy is 12 Apr 2018. It is reported that the cat had circulatory collapse, circulation failure 10 minutes after the administration and died. The animal was in good condition. Necropsy results yieldedpulmonic, arterial hypertrophy of the media, slight bronchiolectasy, alveolar emphysema and a mild acute pneumonia of desquamation, storage of glycogen and fatty degeneration of the Ito cells of the liver, lymphozytic depletion (spleen). The examined animal showed neither macroscopic nor histological alterations, which would indicate the presence of a relevant underlying disease. The alterations in the lung are only minimal (feline asthma with a light, acute, inflammatory component). It is improbable that these alterations have led to the sudden death of the animal. The glycogen storage and the fatty degeneration of the Ito cells in the liver can be looked at as unspecific and do not have a clinical relevance.
An acute heart and circulation failure due to the application of the medicament can not be explained by the pathological findings, so that the reason of the sudden death of the animal remains unclear.

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| Demographic information:<br>Age: 10 Year(s) -<br>Sex : Male<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>0 Day(s) | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Foam in respiratory tract<br>Death<br>Hepatopathy<br>Spleen and reticulo-endothelial system disorder NOS<br>Asthma<br>Loss of consciousness<br>Cardiac insufficiency<br>Pulmonary emphysema | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>unknown<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>Unknown | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

18CH000037



ED_005739D_00014397-00451

ED_005739D_00014397-00452

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Dr Jose Lombardia | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18ES000328 |
| | Address<br>CV Animais<br>Rua Greco, 17<br>Ourense<br>32002<br>Spain | | Address<br>--UNKNOWN-- | |
| | Phone #<br>+34 988233119 | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>04-26-2018 | Date registrant became aware of incident.<br>04-26-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>1084 ESP | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL SPRAY | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE SPRAY | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00453

Internal ID # 18ES000328

Brief description of incident circumstances

Suspected Adverse Event: As reported by the attending vet, a 2 month-old Retriever Labrador female dog received FRONTLINE SPRAY (batch number unknown) topically administered by the owner at home on 26APR2018 for fleas and tick treatment. She had been treated with Telmin and an antiparasitic bath on 24APR2018. After product administration the animal experienced trembling and falling. She was taken to the clinic and the attending vet thought about intoxication. The animal was like absent. Auscultation was correct. The animal was treated with atropine and corticoids, and one minute later the animal collapsed and died.

ED_005739D_00014397-00454

| Demographic information:<br>Age: 2 Month(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>0 Day(s) | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)<br>Atropine and corticoids | List signs/symptoms/adverse effects<br>Muscle tremor<br>Ataxia<br>Impaired consciousness<br>Loss of consciousness<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>Unknown<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>Unknown | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18ES000328

ED_005739D_00014397-00455

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>E BER... | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18FR000610 |
| | Address<br>45<br>France | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>05-02-2018 | Date registrant became aware of incident.<br>05-03-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>FR/V/1803950 2/1994 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL SPRAY | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE SPRAY POMPE (0.5 ML - 1.5 ML) | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>Yes<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00456

Internal ID # 18FR000610

Brief description of incident circumstances

FR-ANMV-18 CPVL 00674: D0: young rabbit applied by farmer with FRONTLINE SPRAY POMPE (size of bottle not specified) before being sold. D2 afternoon: presented by new owner with muscle tremor, prostration, anorexia. Despite therapy, it died during a convulsive episode, less than 12 hours. Duration of reaction (precision): <12 h. Reason for treatment: preventive ? Treatment of SAR: diazepam. Outcome of SAR: Unfavorable. FRONTLINE SPRAY POMPE () : "sprayed"; duration: Once; onset time: < 48 hours.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| Demographic information:<br>Age: 8 Week(s) -<br>Sex : Unknown<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>2 Day(s) | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)<br>Diazepam | List signs/symptoms/adverse effects<br>Muscle tremor<br>Recumbency<br>Anorexia<br>Convulsion<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>"sprayed"; duration: Once; ons<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>1 kg | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

18FR000610

ED_005739D_00014397-00458

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Dr Takahiro Oba | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18JP000194 |
| | Address<br>Oba Animal Hospital Yaizu Hospital<br>2-2-7, Daieicho<br>Yazu-city<br>Shizuoka<br>425-0081, Japan | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>03-13-2018 | Date registrant became aware of incident.<br>05-23-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>9 A 308 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL SPRAY | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE SPRAY | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00459

Internal ID # 18JP000194

Brief description of incident circumstances

As reported by the attending veterinarian, Frontline Spray (Lot number: R02804A, Expiry date: Jun 2019, Date of administration: unknown, external, 1 spray pump or more) was administered to the puppy (Kai dog, BW, age and gender: unknown) by the owner, who is a breeder of a Kai dog. On 23 May 2018, the owner called the animal hospital to report that the puppy died on 23 May 2018. The owner explained that the puppy died with foaming at the mouth this morning after administration of frontline spray. The veterinarian (Assistant director of the animal hospital) asked the owner about the dose etc. and the owner mentioned that the dosage might have been excessive and said that the owner preferred Myfleaguard which the amount of the dose was easier to see. The veterinarian asked the owner to bring the dead puppy and the other puppies that were administered, but the owner got upset for being suspected. There has been no visit to the hospital as of 24 May 2018. Back in 06 Mar 2018, the owner visited the animal hospital without the animal asking for flea prevention. Frontline Spray was ordered to be picked up at a later date. On 13 Mar 2018, the owner visited the hospital and Frontline Spray was prescribed and hair coat conditioner for dog/cat "Humilac" was also purchased. At that time, the owner was instructed that the application should be one spray pump per head at home. Based on the report 18JP000195 (internal reference # FLS18-001), another puppy owned by the same owner experienced similar symptoms and died on May 21, 2018 after Frontline Spray administration (detail unknown).

ED_005739D_00014397-00460

| Demographic information:<br>Age: Unknown -<br>Sex : Unknown<br>Occupation ( if relevant) | Exposure route:<br>other | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>0 Day(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Death<br>Hypersalivation | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>Unknown per Unknown<br>Expose duration:<br>Patient weight:<br>Unknown | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18JP000194

* approximate

ED_005739D_00014397-00461

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Dr Takahiro Oba | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18JP000195 |
| | Address<br>Oba Animal hospital Yaizu Hospital<br>2-2-7 Daieicho<br>Yaizu-city<br>Shizuoka<br>425-0081, Japan | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>03-13-2018 | Date registrant became aware of incident.<br>05-23-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>9 A 308 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL SPRAY | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE SPRAY | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00462

Internal ID # 18JP000195

Brief description of incident circumstances

As reported by the attending veterinarian, Frontline Spray (Lot number: R02804A, Expiry date: Jun 2019, Date of administration: unknown, external, 1 spray pump or more) was administered to the puppy (Kai dog, BW, age and gender: unknown) by the owner, who is a breeder of a Kai dog. On 23 May 2018, the owner called the animal hospital to report that the puppy died on 21 May 2018. The owner explained that the puppy died with foaming at the mouth this morning after administration of frontline spray. The veterinarian (Dr. Takahiro Oba, Assistant director of the animal hospital) asked the owner about the dose etc. and the owner mentioned that the dosage might have been excessive and said that the owner preferred Myfleaguard which the amount of the dose was easier to see. The veterinarian asked the owner to bring the dead puppy and the other puppies that were administered, but the owner got upset for being suspected. There has been no visit to the hospital as of 24 May 2018. Back in 06 Mar 2018, the owner visited the animal hospital without the animal asking for flea prevention. Frontline Spray was ordered to be picked up at a later date. On 13 Mar 2018, the owner visited the hospital and Frontline Spray was prescribed and hair coat conditioner for dog/cat "Humilac" was also purchased. At that time, the owner was instructed that the application should be one spray pump per head at home. Based on the report 18JP000194 (internal reference # FLS18-002), another puppy owned by the same owner experienced similar symptoms and died on May 23, 2018 after Frontline Spray administration (detail unknown).

ED_005739D_00014397-00463

| Demographic information:<br>Age: Unknown -<br>Sex : Unknown<br>Occupation ( if relevant) | Exposure route:<br>other | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>0 Day(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Death<br>Hypersalivation | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>Unknown<br>Expose duration:<br>Patient weight:<br>Unknown | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18JP000195

* approximate

ED_005739D_00014397-00464

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18NL000060 |
| | Address Netherlands | | Address --UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New If update,include date of original submission | Location and date of incident. 12-10-2017 | Date registrant became aware of incident. 04-18-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) REG NL 10142 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s) FIPRONIL 10%/S METHOPRENE 12% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name FRONTLINE COMBO SPOT ON KAT | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation Topicals | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? No<br>Intentional misuse No<br>Applicator certified PCO? No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Base of Skull and btw Shoulder | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00465

Internal ID # 18NL000060

Brief description of incident circumstances

Suspected Adverse Event: As reported by the owner the cat Pasha (Norway Forest cat x Maine Coon, neutered male, 9.5 years, approximately 5 kg) received FRONTLINE COMBO KAT (batch R40505GW, expiry date 042020) topically in the neck administered by the owner on approximately 07112017 and 07122017. A few days after the last application the cat experienced diarrhea and later on also loss of appetite and depression. The owner called the veterinarian for advice. Because the cat started to eat little bits of food the owner decided to wait. The cat died on 24122017. No side-effects where seen after the first application of FL.

ED_005739D_00014397-00466

| Demographic information:<br>Age: 9.5 Year(s) -<br>Sex : Male<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>4 Week(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Diarrhoea<br>Anorexia<br>Lethargy<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>twice, month between<br>Expose duration:<br>Patient weight:<br>5 kg | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18NL000060

* approximate

ED_005739D_00014397-00467

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18NL000100 |
| | Address Netherlands | | Address --UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New If update,include date of original submission | Location and date of incident. 05-27-2018 | Date registrant became aware of incident. 06-01-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) REG NL 8921 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s) FIPRONIL SPOT ON CAT | A.I. (s) | A.I. (s) |
| | Product 1 name FRONTLINE SPOT ON KAT | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Base of Skull and btw Shoulder | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00468

Internal ID # 18NL000100

Brief description of incident circumstances

Suspected Adverse Event: As reported by owner the cat Dartel (Domestic Shorthair, neutered female, approximately 12 years old, 2 kg) received FRONTLINE SPOT ON KAT (batch nr R21306AX, expiry date 072020) topically in the neck administered by the owner on 27052018. A few hours later the cat experienced weakness in the hind legs. The next days the walking improved and because the cat continued to drink the owner did not visit a veterinarian. Since 310502018 the cat was missing. The next day the cat was found by neighbors and was transported to a veterinary clinic. The cat expericienced reduced awareness, was very skinny and severely dehydrated.Tthe cat was euthanized by the veterinarian. No blood work or autopsy has been performed. According to the owner the cat had lost weight in the last period but did not seem sick.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| Demographic information:<br>Age: 12 Year(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>0 Day(s) | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Muscle weakness NOS<br>Weight loss<br>Dehydration<br>Death<br>Impaired consciousness | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose per 1 animal<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>2 kg | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

18NL000100

ED_005739D_00014397-00470

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) unknown | Internal ID # 18SE000073 |
| | Address Sweden | | Address Malmö Djursjukhus Sweden | |
| | Phone # | | Phone # | |
| | Incident Status: New If update,include date of original submission | Location and date of incident. 04-29-2018 | Date registrant became aware of incident. 05-02-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 19848 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name FRONTLINE COMP DOGS S | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation Topicals | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00471

Internal ID # 18SE000073

Brief description of incident circumstances

The 12 years old male pug dog was treated with Frontline Comp (strength unknown so chosen by default) on sunday morgning 29.04.2018. Sunday night the owner was waked up because the dog is having a a kind of seizure. The dog is stiff in the hindlegs, according to the owner the dog is not able to stand but is at the same time walking in circles. The owner takes the dog to the animal hospital, where the dog was euthanalized. MAH has offered to have the dog autopsied, but the dog was already cremated.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| Demographic information:<br>Age: 12 Year(s) -<br>Sex : Male<br>Occupation ( if relevant) | Exposure route:<br>unknown | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>0 Day(s) | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Convulsion<br>Muscle stiffness<br>Ataxia<br>Hyperactivity<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>per Unknown<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>Unknown | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

18SE000073

ED_005739D_00014397-00473

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18TW000025 |
| | Address Taiwan | | Address --UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New If update,include date of original submission | Location and date of incident. 04-23-2018 | Date registrant became aware of incident. 04-23-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 06669 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name FRONTLINE PLUS DOG S | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation Topicals | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00474

Internal ID # 18TW000025

Brief description of incident circumstances

Suspected Adverse Event in Animal Claim: Deceased: Maltese; Female; Intact; 2 years old; 3 kilograms. According to owner, his dog ate a tablet of Heartgard in the morning on 23/04/2018 and no specific finding after that. However, the dog was then found died at noon. The Heartgard tablet was meant to be given on 22/04/2018, but the dog did not eat the tablet, so the teblet was left in the room since 22/04/2018, and the dog ate it on the next morning(23/04/2018). The dog had eaten heartgard a year ago, and no specific finding at that time. Unsure of the heartworm prevention in the past year. The dog was applied with frontline plus recently.

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| Demographic information:<br>Age: 2 Year(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms: | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose per 1 animal<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>3 - 3 kg | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

18TW000025



ED_005739D_00014397-00475

ED_005739D_00014397-00476

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18UK000846 |
| | Address<br>Boehringer Ingelheim<br>Ellesfield Avenue<br>Bracknell<br>Berkshire, RG12 8YS<br>United Kingdom | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 04-01-2011 | Date registrant became aware of incident. 04-24-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>Vm 08327/4132 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL SPOT ON DOG | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE SPOT ON DOG L | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Unknown use | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00477

Internal ID # 18UK000846

Brief description of incident circumstances

As reported by the animal owner, Amber, an approximately 14 year old female neutered Labrador Retriever canine, of unknown weight and condition was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG L) (batch and expiry unknown) via an unknown route by an unknown administrator at an unknown dose for an unknown indication. It is reported that a few years ago (about 7) the animal owner had two dogs that were both treated with FRONTLINE. The FRONTLINE was used for the last 5 years of the animal's lives. One animal, Amber, would always seem hot and pant for 48 hours after application. The animal owner reports that the animal was a delicate dog and things affected her differently. It is reported that the animals were 14 years old when they died (details unknown). Start date of adverse event added for submission purposes only.

ED_005739D_00014397-00478

| Demographic information:<br>Age: 14 Year(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>unknown | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms: | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Hyperthermia<br>Tachypnoea<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>per Unknown<br>Expose duration:<br>5 Year(s)<br>Patient weight:<br>Unknown | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18UK000846

ED_005739D_00014397-00479

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18UK000847 |
| | Address<br>Boehringer Ingelheim<br>Ellesfield Avenue<br>Bracknell<br>Berkshire, RG12 8YS<br>United Kingdom | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 04-01-2011 | Date registrant became aware of incident. 04-24-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>Vm 08327/4132 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL SPOT ON DOG | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE SPOT ON DOG L | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Unknown use | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00480

Internal ID # 18UK000847

Brief description of incident circumstances

As reported by the animal owner, Gale, an approximately 14 year old female neutered Labrador Retriever dog, of unknown weight and condition was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG L, batch and expiry unknown) via an unknown route by an unknown administrator at an unknown dose for an unknown indication. It is reported that a few years ago (about 7) the animal owner had two dogs that were both treated with FRONTLINE. The FRONTLINE was used for the last 5 years of the animal's lives. The animal owner reports that Gale was previously a Guide Dog and took her retirement to heart, was terrible at walking on the lead and was't good at remembering things. It is reported that the animals were 14 years old when they died (details unknown). Start date of adverse event added for submission purposes only.

ED_005739D_00014397-00481

| Demographic information:<br>Age: 14 Year(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>unknown | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms: | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Behavioural disorder NOS<br>Cognitive disorder NOS<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>per Unknown<br>Expose duration:<br>5 Year(s)<br>Patient weight:<br>Unknown | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18UK000847

ED_005739D_00014397-00482

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18UK001032 |
| | Address United Kingdom | | Address --UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New If update,include date of original submission | Location and date of incident. 05-01-2018 | Date registrant became aware of incident. 05-22-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) Vm 08327/4133 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s) FIPRONIL SPOT ON CAT | A.I. (s) | A.I. (s) |
| | Product 1 name FRONTLINE SPOT ON CAT | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00483

Internal ID # 18UK001032

Brief description of incident circumstances

As reported by animal owner, a female cat of unknown name, age , weight, breed and reproductive status, was given FRONTLINE (assumed to be FRONTLINE SPOT ON CAT, batch number and expiry date unknown) from an unknown date, administered by the animal owner, as a regular flea treatment and the animal had fleas close to the skin, which was discovered by the attending vet when the animal was inspected for an unspecified illness. The animal was then put down on 22 MAY 2018, as a tumour was found. No further information was available. Start date of event entered as 01 MAY 2018 for submission purposes.

ED_005739D_00014397-00484

| Demographic information:<br>Age: Unknown -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>unknown | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms: | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Lack of efficacy<br>Malaise<br>Death<br>Neoplasia NOS | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>Unknown per 1 animal<br>Expose duration:<br>Unknown<br>Patient weight:<br>Unknown | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18UK001032

ED_005739D_00014397-00485

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18UK001087 |
| | Address United Kingdom | | Address --UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New If update,include date of original submission | Location and date of incident. 05-01-2018 | Date registrant became aware of incident. 05-30-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) Vm 08327/4132 | EPA Registration # (Product 2) Vm 08327/4269 | EPA Registration # (Product 3) |
| | A.I. (s) FIPRONIL SPOT ON DOG | A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON | A.I. (s) |
| | Product 1 name FRONTLINE SPOT ON DOG M | Product 2 name FRONTLINE PLUS SPOT ON DOGS M | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Unknown use | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00486

Internal ID # 18UK001087

Brief description of incident circumstances

As reported by the animal owner, an approximately 17 year old canine of unknown reproductive status, breed, weight and condition, was administered FRONTLINE ( assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) via an unknown route, to an unknown site by the animal owner at an unknown dose from an unknown date for an unknown indication. The animal owner reports that they have used FRONTLINE for their dog for the last 16 years and have used FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M) (Batch and expiry unknown) since it came out. The animal owner reports that the dog has now passed (coded as death). Start date added for submission purposes only.

ED_005739D_00014397-00487

| Demographic information:<br>Age: 17 Year(s) - *<br>Sex : Unknown<br>Occupation ( if relevant) | Exposure route:<br>unknown | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms: | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>per Unknown<br>Expose duration:<br>Patient weight:<br>Unknown | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18UK001087

* approximate

ED_005739D_00014397-00488

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



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|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Gillian Diesel BVSc MSc PhD MRCVS | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18UK001109 |
| | Address<br>VMD Woodham Lane<br>Addlestone<br>Surrey<br>KT15 3LS<br>United Kingdom | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>05-17-2018 | Date registrant became aware of incident.<br>06-04-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>Vm 08327/4133 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL SPOT ON CAT | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE SPOT ON CAT | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>Yes<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Neck | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00489

Internal ID # 18UK001109

Brief description of incident circumstances

Rabbit was administered spot on treatment on 17 of May 2018. Next day symptoms noticed - lethargic and not eating. Rabbit was taken to Emergency Vet and was treated for potential toxic reaction, and taken home with medication and critical care to encourage eating. 4 days later, Rabbit had first seizure. Taken back to Emergency Vet and kept in hospital for 4 days/nights on IV drip and given Diazepam when required. Rabbit experienced seizures multiple times for those days. On day 7, Rabbit was taken home as eating and acting normal before and after seizures occurred. During the night, Rabbit had 7 seizures; after second one which lasted 3 minutes. Rabbit did not appear to return to normal state and seizures back more frequent.
Rabbit was Put to Sleep the following morning, due to suffering and status epilepticus advised by Vet.
UPDATE 01 JUN 2018: Further information was received by the MAH. As reported by the animals owner, Bunny a 5 month old, intact female Lionhead rabbit, of unknown weight and good health, was given FRONTLINE SPOT ON CAT (batch number and expiry date unknown) on 17 MAY 2018, administered by the animals owner, for the treatment of fleas. The owner reported that the rabbit lived with 4 cats which had caught fleas and so the rabbit caught them too. The vet advised they treat the rabbit with Advantage but the local pet shop did not have any in stock, so they were sold FRONTLINE instead. The rabbit had an unspecified vaccination at the vets the same day. The rabbit became quiet and off their food that day on 17 MAY 2018 but the vet advised that this was normal after a vaccination. The next day on 18 MAY 2018 the rabbit was lethargic, had been off its food for 24 hrs and was very quiet, not active and not running around. The owner then read the FRONTLINE box warning which said it was not suitable for rabbits. The owner took the rabbit straight to the emergency vets. A specialist was called who advised the vet to put the rabbit on IVFT and clip and
bathe in washing up liquid, the vet however was adamant that not eating was the main issue at the time, so just had the rabbits fur clipped and the rabbit bathed, Metoclopramide 5 ml was dispensed to be given to the rabbit three times a day from 18 MAY 2018 to 22 MAY 2018. Over that weekend the rabbit improved and started eating critical care from the syringe and became more active, then started to eat on its own. On 21 MAY 2018 the rabbit had a seizure which lasted for 30 seconds, it was the first seizure that the owner knew about. The animal was taken straight back to the vets, and was admitted from 21 MAY 2018 until 24 MAY 2018, was given IVFT and Diazepam, the rabbit was having seizures every day, until the rabbit was having them every 12 hours the same time in the evening and in the night. On 24 MAY 2018 the vets advised that the rabbit was better, the animal was well and the owner took the rabbit home, the rabbit was given Phenobarbital to prevent further seizures. However the rabbit then went into status epilepticus. On 25 May 2018 the owner took the rabbit to the vets and the rabbit was put to sleep that morning.

ED_005739D_00014397-00490

| Demographic information:<br>Age: 5 Month(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>0 Day(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)<br>IV drip and given Diazepam | List signs/symptoms/adverse effects<br>Death<br>Lethargy<br>Anorexia<br>Convulsion<br>Malaise<br>Epileptic seizure | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 dosage form per 1 animal<br>Expose duration:<br>10 Second(s)<br>Patient weight:<br>1.7 kg | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18UK001109

* approximate

ED_005739D_00014397-00491

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



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|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Sara Siddiqui | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18UK001283 |
| | Address<br>Village Vet - Park Veterinary Group<br>116 Regents Park Road<br>Finchley<br>Greater London<br>N3 3HY, United Kingdom | | Address<br>--UNKNOWN-- | |
| | Phone #<br>02083431433 | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>06-15-2018 | Date registrant became aware of incident.<br>06-20-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>Vm 08327/4268 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS SPOT ON DOGS L | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>No<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00492

Internal ID # 18UK001283

Brief description of incident circumstances

As reported by the attending veterinary surgeon, Honey, a female neutered Golden Retriever canine, born 30 JUN 2006, weighing 29.4 kg and in good condition, was administered FRONTLINE PLUS SPOT ON DOGS L (batch R60906AR, expiry MAR 2020) topically by the animal owner at a dose of 1 pipette on 14 JUN 2018 as preventative care. The animal has a history of Arthritis and received Gabapentin and Loxicom. The following day, 15 JUN 2018, the animal was not herself and was lethargic but her appetite was good. Bloods were taken on this day and ALKP was 303 (elevated slightly) and Urea was 15.9 (elevated), PCV was 32 percent Platelets were 138 and Albumin was 30. The animal was not treated and was better over the weekend. On Monday, 18 JUN 2018 the animal had a walk and was eating, and the animal owner took the other dogs out. When they returned the animal was collapsed lying laterally. The animal had abdominal discomfort - nothing abnormal was detected on abdominal cystocentesis - no blood back - but the vet suspected a bleed. The animal's PCV was 27 percent and Platelets was 78 percent (both dropped from previous bloods), WBC were down to 12 and Albumin 32. The animal's temperature was 37.9 and was only lifting the head, was tachypnoeic with abdominal distension and pale mucus membranes. The attending vet reports that the animal was a very quiet dog in nature who had been 'old since a puppy and was not very emotionally resilient. The animal owner opted for the animal to be put to sleep (euthanased) on a quality of life basis. No post mortem examination and no scans of abdomen.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| Demographic information:<br>Age: 11 Year(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>1 Day(s) | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Malaise<br>Lethargy<br>Abnormal test result<br>Renal insufficiency<br>Collapse NOS<br>Abdominal pain<br>Distension of abdomen<br>Anaemia NOS<br>Thrombocytopenia<br>Leucopenia<br>Tachypnoea<br>Pale mucous membrane<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 dosage form per 1 animal<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>29.4 kg | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

18UK001283

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18US008595 |
| | Address<br>COSTA MESA<br>CA<br>92626<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 03-28-2018 | Date registrant became aware of incident. 05-08-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 65331-4 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 12% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name FRONTLINE PLUS CATS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? Yes<br>Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00495

Internal ID # 18US008595

Brief description of incident circumstances

Suspected Adverse Event: On 8 May 2018, the owner reported the following event for Max, 14 year old, 25 pound, neutered male, Maine Coon feline.
28 Mar 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades.
Unknown date: The cat experienced intense itching, hair loss, and lethargy.
1 Apr 2018: The pet was presented to the clinic. The veterinarian administered an unknown oral flea preventative.
7 Apr 2018: The cat passed away.
The cat also received FRONTLINE on 7 Mar 2018 and 14 Feb 2018 but no symptoms presented. No further medical information is expected.

ED_005739D_00014397-00496

| Demographic information:<br>Age: 14 Year(s) -<br>Sex : Male<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>6 Week(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)<br>Oral flea preventative | List signs/symptoms/adverse effects<br>Pruritus<br>Alopecia<br>Lethargy<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose per 1 animal<br>Expose duration:<br>6 Week(s)<br>Patient weight:<br>25 lbs | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US008595

* approximate

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18US018105 |
| | Address<br>DELPHI<br>IN<br>46923<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 03-11-2018 | Date registrant became aware of incident. 04-04-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 65331-5 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS DOG 23-44 LBS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? No<br>Intentional misuse No<br>Applicator certified PCO? No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00498

Internal ID # 18US018105

Brief description of incident circumstances

Suspected Adverse Event: On 4 Apr 2018, the owner reported the following event for a Corgi canine (all other signalments unknown).
10 Mar 2018: One vial of FRONTLINE PLUS DOG 23-44 LBS (R60811AL) was applied at an unknown location.
Unknown date: The dog experienced vomiting, anorexia, increased urinating, and increase drinking. The pet was presented to the clinic. The attending veterinarian administered B12 injection and prescribed an unknown medication.
22 Mar 2018*: The dog experienced anal bleeding and shortness of breath. The dog was euthanized.
No further medical information is expected.
Update 10 Apr 2018 NH: Owner called to report the event for Jack, 10 year old, 40 pound, neutered male, Welsh Corgi canine.
10 Mar 2018: The product was applied between the shoulder blade for the first time.
11 Mar 2018: The symptoms presented.
Update 27 Jun 2018: Upon review the route of administration in the product screen was corrected.

ED_005739D_00014397-00499

| Demographic information:<br>Age: 10 Year(s) -<br>Sex : Male<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>1 Day(s) | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)<br>B12 injection, and | List signs/symptoms/adverse effects<br>Emesis<br>Anorexia<br>Polyuria<br>Polydipsia<br>Rectal haemorrhage<br>Dyspnoea<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>40 lbs | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US018105

ED_005739D_00014397-00500

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) Dr UNKNOWN | Internal ID # 18US022667 |
| | Address LANSDALE PA 19446 U.S.A | | Address HARLEYSVILLE VETERINARY HOSPITAL 391 MAIN ST HARLEYSVILLE PA, 19438 U.S.A | |
| | Phone # | | Phone # 215-256-4664 | |
| | Incident Status: New If update,include date of original submission | Location and date of incident. 01-01-2018 | Date registrant became aware of incident. 04-24-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 65331-5 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name FRONTLINE PLUS DOG 5-22 LBS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Mouth | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00501

Internal ID # 18US022667

Brief description of incident circumstances

Suspected Adverse Event: On 24 Apr 2018, the animal owner reported the following event for an unknown canine of unknown signalment weighing 9.0 pounds.
Unknown dates: the canine received HEARTGARD PLUS (68 MCG/57 MG) (lot and expiration) one chew administered orally monthly and FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown) one vial applied topically monthly for an unknown length of time. It is unknown if the canine experienced any outward symptoms. It is unknown if any treatments were administered. The canine passed away an unknown time later.
The health status of the canine at the time of administration is unknown. No further medical information expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| Demographic information:<br>Age: Unknown -<br>Sex : Unknown<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>0 Day(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose per 1 animal<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>9.0 lbs | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

18US022667

* approximate

ED_005739D_00014397-00503

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Malinda unknown | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18US025087 |
| | Address<br>unknown<br>RICE<br>WA<br>99167<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>04-28-2018 | Date registrant became aware of incident.<br>05-02-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>65331-5 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS DOG 23-44 LBS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>Yes<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00504

Internal ID # 18US025087

Brief description of incident circumstances

Suspected Adverse Event: On 2 May 2018, the owner reported the following event for Bear, an approximately 10 year old, approximately 60 pound, intact male, Retriever (Labrador, Black).
27 Apr 2018: 1 vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was given to the dog topically between the shoulder blades, by the owner. The dog has been on the product for an unknown amount of time.
28 Apr 2018: The dog started vomiting, was lethargic, and was drinking a lot of water.
The dog was not seen by a veterinarian or given any treatment. The dog died on 5 May 2018. No further medical information expected.

ED_005739D_00014397-00505

| Demographic information:<br>Age: 10 Year(s) - *<br>Sex : Male<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms: | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Emesis<br>Lethargy<br>Death<br>Polydipsia | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>Patient weight:<br>60 lbs | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US025087

* approximate

ED_005739D_00014397-00506

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Dr Elizabeth PARKER | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18US030660 |
| | Address<br>NOKOMIS PET CLINIC<br>2917 E 42ND ST<br>MINNEAPOLIS<br>MN, 55406<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone #<br>612-767-4546 | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>05-21-2018 | Date registrant became aware of incident.<br>05-22-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>65331-4 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 12% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS CATS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>No<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00507

Internal ID # 18US030660

Brief description of incident circumstances

Suspected Adverse Event: On 22 May 2018, the veterinarian reported the following event for Cinder, 13 year old, 12 pound, spayed female, Domestic Shorthair feline.
21 May 2018: One vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. After 2 hours the cat passed away.
No further medical information is expected.
UPDATE 23 May 2018: The veterinarian called to make the following update to the case:
The cat ingested the FRONTLINE PLUS after he groomed himself, he was able to reach the product where it was applied. When the owner came across the diceased cat there was some drooling in his mouth. No further information available at this time.
UPDATE 21 Jun 2018: Per medical record, a necropsy was performed on 23 May 2018 with the following conclusion: The specific cause of the sudden, unexpected death in this cat was not apparent after gross and histologic examination. The most significant necropsy finding in this cat involved increased left ventricular moderator bands with mild myocardial hypertrophy.This is suggective of cardimyopathy; however, there was no obvious evidence of heart failure making the clinical significance unknown. Renal changes are suggestive of chronic kidney disease and due to the mild nature of the lesions are likely unrelated to the cause of death. The clinical significance of the reported use of FRONTLINE in the time period prior to death is unknown. No further information is expected.

Voluntary Industry Reporting Form for 6(a)(2) Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| Demographic information:<br>Age: 13 Year(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>12 Month(s) | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Hypersalivation<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>12 Month(s)<br>Patient weight:<br>12 lbs | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #

18US030660

ED_005739D_00014397-00509

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Bree DAGENAIS | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18US036240 |
| | Address<br>COUNTRY GARDEN VETERINARY CLINIC<br>2310 BROOKLYN RD<br>JACKSON<br>MI, 49203<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone #<br>517-783-5851 | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>06-07-2018 | Date registrant became aware of incident.<br>06-13-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>65331-4 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 12% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS CATS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>No<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Unknown use | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00510

Internal ID # 18US036240

Brief description of incident circumstances

Suspected Adverse Event: On 13 Jun 2018, the veterinarian reported the following event for Smokey, a 9 pound, 10 year old*, neutered male Domestic Shorthair.
1 Jun 2010*: Smokey started on the FRONTLINE PLUS CATS (R40101AW).
7 Jun 2018: The most recent dose was applied in an unknown location. About 3 hours later, the pet seemed disoriented and wobbly in his hind legs.
8 Jun 2018: The symptoms were ongoing so the owner attempted to wash the product off with an unknown shampoo. The owner also noticed that the pet's eyes were red.
9 Jun 2018: Smokey presented to the clinic and was still ataxic in his hind legs. The vet stated that he had bilateral retinal detachment and mild congestion of conjunctiva in both eyes. A negative FIV test was performed via an unknown test. A complete CBC and blood chemistry was performed with results WNL. A toxoplasmosis test was performed via Antech, but results are unknown at this time. The pet was treated with clindamycin and Neo-Poly-Dex eye drops.
10 Jun 2018*: The pet remained in clinic. The vet noticed that the bladder was turgid. Urination was expressed via vet manually.
11 Jun 2018: Radiographs were performed which were deemed unremarkable. He was given I/V fluids.
13 Jun 2018: The pet experienced a seizure.
The pet is still in clinic with ongoing symptoms. The pet has received the product seasonally since Jun 2010* without any adverse effect. No further information at this time.
UPDATE 13 Jun 2018: Per the veterinarian, the pet was euthanized. A necropsy is planned. No further information at this time.
UPDATE 12 Jul 2018: Per medical record, the pet tested pos via IGG titer for toxoplasmosis. Necropsy results revealed lymphoma affecting the eye, heart and lungs, which could have caused an embolic event resulting in the other clinical signs and the pet's quick demise. There was no connection between the FRONTLINE PLUS CATS and the pet's condition. No further medical information expected.

ED_005739D_00014397-00511

| Demographic information:<br>Age: 10 Year(s) - *<br>Sex : Male<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>8 Year(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)<br>clindamycin, Neo-Poly- | List signs/symptoms/adverse effects<br>Ataxia<br>Disorientation<br>Eye redness<br>Conjunctivitis<br>Retinal detachment<br>Urinary retention<br>Convulsion<br>Death<br>Lymphoma<br>Toxoplasmosis | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>Patient weight:<br>9 lbs | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US036240

* approximate

ED_005739D_00014397-00512

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18US036378 |
| | Address<br>SHERMAN OAKS<br>CA<br>91423<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 08-01-2017 | Date registrant became aware of incident. 06-13-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 65331-5 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS DOG 23-44 LBS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? No<br>Intentional misuse No<br>Applicator certified PCO? No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00513

Internal ID # 18US036378

Brief description of incident circumstances

Suspected Adverse Event: On 13 Jun 2018, the owner reported the following event for Emmy, 12 year old, 24 pound, spayed female, Shetland Sheep Dog canine.
1 Aug 2017*: One vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was applied between the shoulder blades. After a few hours the pet experienced intense itching. The pet was not presented to the clinic. The owner bathed the pet and applied an anti itch ointment.
Sept 2017*: The pet passed away.
The dog has received the product on prior unknown date and no symptoms presented. There is one other dog in the household that did not receive the product and was asymptomatic. No further medical information is expected.

ED_005739D_00014397-00514

| Demographic information:<br>Age: 12 Year(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms: | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)<br>Bath and ointment | List signs/symptoms/adverse effects<br>Pruritus<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>Patient weight:<br>24 lbs | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US036378

ED_005739D_00014397-00515

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18US037420 |
| | Address<br>MIAMI<br>FL<br>33186<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 06-14-2018 | Date registrant became aware of incident. 06-18-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 65331-5 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s) FIPRONIL 10%/S METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name FRONTLINE PLUS DOG 5-22 LBS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? No<br>Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating). See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff). See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00516

Internal ID # 18US037420

Brief description of incident circumstances

Suspected Adverse Event: On 18 Jun 2018, a family member reported the following event for Molly, an approximately 11 year old, approximately 10 pound, female, Maltese (all other signalments unknown).
10 Jun 2018: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (R60830AL) was given to the dog topically, between the shoulder blades, by the family member. It is unknown if this was the first dose received.
14 Jun 2018: The dog died on its own.
The dog was not seen by a veterinarian or given any treatment. Prior to the application, the dog was missing hair and was thin from weight loss (unknown cause). No further medical information expected.

ED_005739D_00014397-00517

| Demographic information:<br>Age: 11 Year(s) - *<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>4 Day(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>Patient weight:<br>10 lbs | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US037420

* approximate

ED_005739D_00014397-00518

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18US039431 |
| | Address<br>CINCINNATI<br>OH<br>45230<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 06-23-2018 | Date registrant became aware of incident. 06-25-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 65331-4 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 12% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name FRONTLINE PLUS CATS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? Yes<br>Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00519

Internal ID # 18US039431

Brief description of incident circumstances

Suspected Adverse Event: On 25 Jun 2018, the owner reported the following event for Sassy, 17 year old, 6 pound, spayed female, Siamese feline.
23 Jun 2018: One third of a vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades. The pet experienced foaming at the mouth and vomiting. It is believed that the pet ingested the product.
24 Jun 2018: The pet was presented to the clinic. It is unknown if any treatment was provided.
25 Jun 2018: Symptoms are still ongoing.
The pet received FRONTLINE on prior unknown dats and no symptoms presented. There are two other cats in the household that also had the product and experienced symptoms (see case 18US039756, 18US039758). No further medical information is expected.
UPDATE 26 Jun 2018: Owner called to report symptoms have worsened. The pet is experiencing anorexia, and lethargy. The cat is still at the clinic in the intensive care unit. The attending veterinarian is treating with fluids and unknown medications. No further medical information is expected.
UPDATE 25 Jul 2018: Per information reported by the retailer, the cat is now deceased. It is unknown the circumstances under which the cat expired.
No further information is available at this time.

ED_005739D_00014397-00520

| Demographic information:<br>Age: 17 Year(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms: | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Hypersalivation<br>Emesis<br>Anorexia<br>Lethargy<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>Patient weight:<br>6 lbs | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US039431

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18US040451 |
| | Address<br>PLYMOUTH<br>MI<br>48170<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 10-01-2014 | Date registrant became aware of incident. 06-27-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 65331-5 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS DOG 45-88 LBS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? No<br>Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00522

Internal ID # 18US040451

Brief description of incident circumstances

Suspected Adverse Event: On 27 June 2018, the owner reported the following event for Benny, a 14 year old, 38 pound, intact male Shetland Sheep Dog.
*1 Oct 2010: One dose of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown) was applied to the dog per label.
*1 Oct 2014: The dog developed a tumor at his neck that never went away.
*1 May 2018: The dog died of cancer.
The dog had FL the month prior with no issues. The dog also was either on Sentinel or Interceptor at the time. No further medical information expected.

ED_005739D_00014397-00523

| Demographic information:<br>Age: 14 Year(s) -<br>Sex : Male<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>4 Year(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Neoplasia NOS<br>Death | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>Patient weight:<br>38 lbs | | | |
| Human severity category<br>D-A | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US040451

* approximate

ED_005739D_00014397-00524

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Alan Unknown surname | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18NZ000165 |
| | Address<br>Ex. 6 PP – personal address<br>New Zealand | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>04-10-2018 | Date registrant became aware of incident.<br>05-09-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>A9009 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS DOG M | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation<br>Topicals | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>Yes<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00525

Internal ID # 18NZ000165

Brief description of incident circumstances

As reported by the owner, three dogs were treated with FRONTLINE PLUS FOR DOGS (unknown batch and expiry) by the owner on 10 April 2018 and again on 3 May 2018. Previous flea treatment was applied during November 2018 with a different product. The owner is still seeing 2-3 fleas on the one of the dogs, 'Lucy' a 8kg female bischon frise. All of the dogs spend time in the house and garden.

ED_005739D_00014397-00526

| Demographic information:<br>Age: --UNKNOWN--<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>0 Day(s) | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Lack of efficacy | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose per 1 animal<br>Expose duration:<br>23 Day(s)<br>Patient weight:<br>8 kg | | | |
| Human severity category<br>D-D | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18NZ000165

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18US021201 |
| | Address<br>EPWORTH<br>IA<br>52045<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 10-01-2017 | Date registrant became aware of incident. 04-18-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 65331-5 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS DOG 5-22 LBS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? Yes<br>Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00528

Internal ID # 18US021201

Brief description of incident circumstances

Suspected Adverse Event: On 18 Apr 2018, the owner reported the following event for Rigley, 10 month, 9 pound, neutered male, Bichon Frise canine.
Oct 2017*: Half a vial of FRONTLINE PLUS DOG 5-22 LBS (R60308AL) was applied between the shoulder blades. After a few hours the dog experienced lethargy. The pet was not presented to the clinic. The owner administered Benadryl.
Unknown date: The pet recovered.
The pet received FRONLTINE monthly since 31 Aug 2017* and no symptoms presented. No further medical information is expected.

ED_005739D_00014397-00529

| Demographic information:<br>Age: 10 Month(s) -<br>Sex : Male<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>31 Day(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)<br>Benadryl | List signs/symptoms/adverse effects<br>Lethargy | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>Patient weight:<br>9 lbs | | | |
| Human severity category<br>D-D | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US021201

* approximate

ED_005739D_00014397-00530

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Dr WINIKOFF | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18US023419 |
| | Address<br>ROCKLAND HOLISTIC VET CARE<br>626 ROUTE 303<br>BLAUVELT<br>NY, 10913<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone #<br>845-348-7729 | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>01-01-2016 | Date registrant became aware of incident.<br>04-13-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>65331-5 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS DOG 0-22 LBS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)). | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00531

Internal ID # 18US023419

Brief description of incident circumstances

Suspected Adverse Event: On 13 Apr 2018, a veterinarian reported the following event for an Unknown 20 pound, *5 year old, neutered male Bichon Frise Mix.
On an unknown date, the canine received FRONTLINE (unsubstantiated)(lot and expiration unknown) and an unknown amount of time later began twitching, labored breathing and acting out of it. It is unknown if the canine presented to the clinic for treatment and current status is unknown.
The veterinarian also reported another case for this canine, 18US020373. No further medical information availablle.
Update 30 Apr 2018: The reporter did not indicate the symptoms were ongoing at the time the event in case18US020373 occurred, so an approximate event end date was entered for this case.

ED_005739D_00014397-00532

| Demographic information:<br>Age: 5 Year(s) -<br>Sex : Male<br>Occupation ( if relevant) | Exposure route:<br>unknown | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>0 Day(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Muscle tremor<br>Dyspnoea<br>Behavioural disorder NOS | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>Unknown<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>20.0 lbs | | | |
| Human severity category<br>D-C | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US023419

* approximate

ED_005739D_00014397-00533

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18US029369 |
| | Address<br>unknown<br>ONTARIO<br>CA<br>91762<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 05-15-2018 | Date registrant became aware of incident. 06-05-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 65331-5 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS DOG 5-22 LBS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? No<br>Intentional misuse No<br>Applicator certified PCO? No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00534

Internal ID # 18US029369

Brief description of incident circumstances

Suspected Adverse Event: On 5 Jun 2018 the owner reported the following event for an unknown canine.
1 May 2018: An unknown amount of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was given to the dog (unknown route and site of application), by the owner. This was the first dose applied. The dog had fleas.
15 May 2018*: The dog started chewing and pulling out fur.
It is unknown if the dog was seen by a veterinarian or given any treatment. The dog's current status is unknown. No further medical information expected.
UPDATE 19 Jul 2018: The owner reported the following for Gi Gi, a 15 year old, spayed female, Bichon Frise (all other signalments unknown).
1 May 2018: 1 vial of the product (R60830AL) was given to the dog topically between the shoulder blades.
15 May 2018*: The symptoms started. The owner also reported lethargy.
24 May 2018*: The dog recovered.
The dog was seen by the veterinarian and given AB injection, Amoxicillin, Vetalog injection, and an unknown skin treatment. There was a new puppy brought into the home around that time and did also receive a treatment but did not have any symptoms. No further medical information expected.

ED_005739D_00014397-00535

| Demographic information:<br>Age: 15 Year(s) - *<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>2 Week(s) | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient)<br>AB injection, | List signs/symptoms/adverse effects<br>Pruritus | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>0 Day(s)<br>Patient weight:<br>Unknown | | | |
| Human severity category<br>D-D | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US029369

* approximate

ED_005739D_00014397-00536

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name | Submission date. 08-06-2018 | Contact person (if different than reporter) | Internal ID # 18US033206 |
| | Address<br>CLERMONT<br>FL<br>34711<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone # | | Phone # | |
| | Incident Status: New<br>If update,include date of original submission | Location and date of incident. 05-08-2018 | Date registrant became aware of incident. 06-01-2018 | Was incident part of larger study ? No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1) 65331-5 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS DOG 5-22 LBS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed? No<br>Intentional misuse No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO? No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

ED_005739D_00014397-00537

Internal ID # 18US033206

Brief description of incident circumstances

Suspected Adverse Event: On 1 June 2018, the owner reported the following event for Chelsea, a 3 year old, 14 pound, spayed female Bichon Frise.
1 May 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (P62719AL) was applied to the dog per label.
8 May 2018: The dog developed a yellow spot at the site of application.
4 June 2018: The spot is appearing to fade, but it is still apparent.
The dog has been on FL all her life with no issues, she has not been seen by the vet for her ongoing symptom. No further information available.

ED_005739D_00014397-00538

| Demographic information:<br>Age: 3 Year(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>3 Year(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Application site hair change | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>3 Year(s)<br>Patient weight:<br>14 lbs | | | |
| Human severity category<br>D-D | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US033206

* approximate

ED_005739D_00014397-00539

# Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area.



| | | | | |
|---|---|---|---|---|
| Row 1 Administrative Data | Reporter Name<br>Corinne Unknown | Submission date.<br>08-06-2018 | Contact person (if different than reporter) | Internal ID #<br>18US033702 |
| | Address<br>AMERICAN ANIMAL HOSPITAL<br>11030 EMMET ST<br>OMAHA, NE<br>68164<br>U.S.A | | Address<br>--UNKNOWN-- | |
| | Phone #<br>402-493-6767 | | Phone # | |
| | Incident Status:<br>New<br>If update,include date of original submission | Location and date of incident.<br>06-01-2018 | Date registrant became aware of incident.<br>06-04-2018 | Was incident part of larger study ?<br>No |

| | | | |
|---|---|---|---|
| Row 2 Pesticide(s) Involved | EPA Registration # (Product 1)<br>65331-5 | EPA Registration # (Product 2) | EPA Registration # (Product 3) |
| | A.I. (s)<br>FIPRONIL 10%/S<br>METHOPRENE 9% SPOT ON | A.I. (s) | A.I. (s) |
| | Product 1 name<br>FRONTLINE PLUS DOG 0-22 LBS | Product 2 name | Product 3 name |
| | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? | Exposed to concentrate prior to dilution ? |
| | Formulation | Formulation | Formulation |

| | | | |
|---|---|---|---|
| Row 3 Incident Circumstances | Evidence label directions were not followed?<br>No<br>Intentional misuse<br>No | Incident site: (Examples include home, yard, school, industrial, nursery/ greenhouse, surface water, commercial turf, building/office, forest/woods, agricultural (specify crop), right-of-way, (rail, utility, highway)).<br>Between the shoulders (topical | Situation (act of using product) :(examples including mixing/loading, reentry, application, transportation, repair, maintenance of application equipment, manufacturing/formulating).<br>See Incident Description Notes |
| | Applicator certified PCO?<br>No | | |
| | How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff).<br>See Incident Description | Brief description of incident circumstances | |

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Internal ID # 18US033702

Brief description of incident circumstances

Suspected Adverse Event: On 4 Jun 2018, the owner reported the following event for Princess, an 8 year old, 19.9 pound, spayed female, Bichon Frise.
2010*: The dog started on 1 vial of FRONTLINE PLUS DOG 0-22 LBS (lot unknown) given to the dog topically between the shoulder blades, by the owner. The frequency of application is unknown.
24 May 2018: The dog started on Prednisone.
28 May 2018*: The dog was given another dose of Frontline Plus.
29 May 2018: The dog got the last dose of Prednisone.
1 Jun 2018: The fur at the application site turned yellow. There was no skin irritation.
The dog was seen by the veterinarian but was not given any treatment. The symptoms are ongoing. The dog is groomed regularly. The dog has a history of allergies. No further medical information expected.

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| Demographic information:<br>Age: 8 Year(s) -<br>Sex : Female<br>Occupation ( if relevant) | Exposure route:<br>Topical / Cutaneous | Was adverse effect result of suicide/homicide or attempted suicide/homicide?<br>No | Was protective clothing worn (specify) ? |
|---|---|---|---|
| If female, pregnant ? | Was exposure occupational?<br>If yes, days lost due to illness: | Time between exposure and onset of symptoms:<br>8 Year(s) * | |
| Type of medical care sought (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient) | List signs/symptoms/adverse effects<br>Application site hair change | | If lab tests were performed, list test names and results(If available submit report).<br>None reported |
| Exposure data:<br>Amount of pesticide:<br>1 Dose<br>Expose duration:<br>Patient weight:<br>19.9 lbs | | | |
| Human severity category<br>D-D | | | |

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID #
18US033702

* approximate

ED_005739D_00014397-00542

**From:** helpdesk@epacdx.net
**To:** McAlister,Leann (AH GI RA PV) BIAH-US-D
**Subject:** CDX PSP Package Transmitted to OPP
**Date:** Thursday, March 25, 2021 2:19:17 PM

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**CAUTION! Please do not click links or open attachments unless you recognize the sender**, this email is from an **External Sender** (outside Boehringer-Ingelheim)

Your PSP package (20210325_Resubmission_CoverLetter_EPAAggregateReport2Q18) for BOEHRINGER INGELHEIM ANIMAL HEALTH USA INC. (65331) has been successfully transmitted to OPP.

Below are the application(s) included in this package and their tracking number(s):
Sec3-6(a)(2)-000001: CDX_2021_003338
Sec3-6(a)(2)-000002: CDX_2021_003339
Sec3-6(a)(2)-000003: CDX_2021_003340
Sec3-6(a)(2)-000004: CDX_2021_003341
Sec3-6(a)(2)-000005: CDX_2021_003342
Sec3-6(a)(2)-000006: CDX_2021_003343

Company Name: BOEHRINGER INGELHEIM ANIMAL HEALTH USA INC.
Company Number: 65331

If you have questions concerning this message, you may contact the CDX Help Desk by email at helpdesk@epacdx.net or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

CDX Homepage
https://cdx.epa.gov

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United States Environmental Protection Agency - Central Data Exchange