

65331-5

08/28/2013

1/22



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Karen Mardis
Senior Manager, Regulatory Affairs North America
Merial Limited
3239 Satellite Blvd
Duluth, GA 30096

AUG 28 2013

Subject: Merial Limited submissions implementing label changes to pet spot-on products Fipaira for Cats, Fipaira for Dogs, Frontline Plus for Cats, and Frontline Plus for Dogs
EPA Reg. Nos. 65331-2, 65331-3, 65331-4, and 65331-5
EPA Decision Nos. 479946 - 479949 and 471039

Dear Ms. Mardis,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the label requirements listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled. If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

Stamped copies of the labels are enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at keller.kaitlin@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosure: Labels stamped "Accepted"

2/22

Reason to issue: Label Mitigation Changes
EPA Reg. No. 65331-5

Amendment
Date: 7/11/13
Supersedes: 7/2/13

Master Label
1x, 3x, and 6x presentations

Includes label text for four different applicator sizes corresponding to four dog weight ranges, and including a 1x, 3x and 6x applicator presentation. Due to space limitations the layout of the 1x hanging card may differ from the 3x and 6x cartons (NOTE: The 1x hanging card will not utilize a carton or compliance cards, so all required information will be located on the Insert, blister pack or pipette for the 1x presentation).

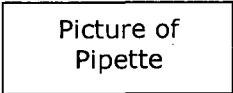
[Optional text appears in brackets-the final product label may include some or all of the optional text on the front, back, side panels, or insert.]

FRONTLINE® Plus FOR DOGS
[ABN] [FRONTLINE® Top Spot® FOR DOGS]

(Note: font size of FOR DOGS will be 40% of the size of the largest letter in the brand name on the front panel)
(FRONT PANEL OF 3X and 6X CARTON)

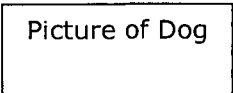
[Full brand name]

[3][6] doses



Kills fleas, flea eggs & larvae, ticks, [&] chewing lice [& mosquitoes]

- Fast-acting
- Long-lasting
- Waterproof

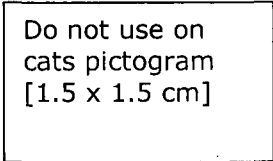


Kills ticks, including those that may transmit Lyme disease

[For use ONLY on DOGS & PUPPIES 8 Weeks or Older and **5-22lbs**]
[For use ONLY on DOGS **23 to 44lbs**]
[For use ONLY on DOGS **45 to 88lbs**]
[For use ONLY on DOGS **89 to 132lbs**]

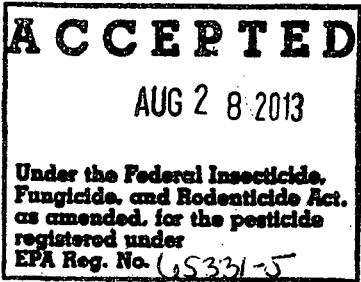
ACTIVE INGREDIENTS:

Fipronil.....9.8%
(S)-methoprene.....8.8%
INERT INGREDIENTS.....81.4%
TOTAL100%



NET CONTENTS: X fl oz (Y-X fl oz applicators)

DO NOT USE ON CATS



3/
r

Reason to issue: Label Mitigation Changes
EPA Reg. No. 65331-5

Amendment
Date: 7/11/13
Supersedes: 7/2/13

(FRONT PANEL OF 3X and 6X CARTON) (Cont'd)

[[3][6]-0.023 fl oz (0.67 ml) applicators]
[[3][6]-0.045 fl oz (1.34 ml) applicators]
[[3][6]-0.091 fl oz (2.68 ml) applicators]
[[3][6]-0.136 fl oz (4.02 ml) applicators]

SEE INSERT FOR FIRST AID AND PRECAUTIONARY STATEMENTS
KEEP OUT OF REACH OF CHILDREN

CAUTION

(LEFT INNER PANEL OF 3X and 6X CARTON)

[Full brand name]

[Full or partial brand name] is:

- Fast-acting
- Long-lasting
- Waterproof

One spot application is all that's needed:

[Full or partial brand name] spreads from the single point of application, rapidly covering the entire dog and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing [Full or partial brand name] onto the skin and hair coat, so it keeps working even if the dog gets wet.

Fleas, flea eggs & larvae, ticks and chewing lice are killed quickly after coming into contact with a treated dog. Fleas and ticks do not need to bite the dog in order to die.

[Full or partial brand name]:

Fleas

- Kills fleas, flea eggs and flea larvae
- Prevents all flea stages (eggs, larvae, pupae) from developing
- Stops existing infestations and prevents establishment of new infestations
- Kills fleas which may cause flea allergy dermatitis

Ticks

- Kills all life stages of ticks (larva, nymph and adult), including deer ticks (*Ixodes scapularis*), brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*) and lone star ticks (*Amblyomma americanum*)
- Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases

Lice

- Rapidly eliminates chewing lice infestations

[Mosquitoes]

- [Kills mosquitoes]

Mites

- Aids in the control of sarcoptic mange infestations

[Full or partial brand name] is approved for use on all dogs, including:

- Breeding, pregnant, and lactating bitches
- Puppies as young as 8 weeks and weighing at least [5 lbs.] [23 lbs.] [45 lbs.] [89 lbs.]



Adult Fleas



Flea Eggs



Flea Larvae



Ticks



Chewing Lice



[Mosquitoes]

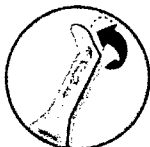
(RIGHT INNER PANEL OF 3X and 6X CARTON)

How to Apply [Full or partial brand name]



Step 1. To REMOVE Applicator

Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.



Step 2. OPEN Applicator

Hold upright with foil side toward you and snap applicator tip.



Step 3. APPLY [Full or partial brand name]

Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the dog's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry. Do not allow your dog to ingest this product. [Do not apply to dogs weighing less than [5 lbs.] [23 lbs.] [45 lbs.] [89 lbs.] or younger than 8 weeks of age.][Do not use two applicators for dogs weighing more than 132 lbs.] Do not use more than one application per dog per month.

Questions or Comments?

Call: 1-800-660-1842.

**Monday-Friday, 8am-8pm EST or
visit us at www.FRONTLINE.com**

6/22

(BACK PANEL OF 3X and 6X CARTON)

[Full brand name]

[Full or partial brand name] provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice, [and] sarcoptic mites [and mosquitoes] for use ONLY on [dogs and puppies 8 weeks or older and 5-22 lbs.][dogs weighing 23-44 lbs.] [dogs weighing 45-88 lbs.][dogs weighing 89-132 lbs.].

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. Pets may experience some temporary irritation at the site of application. Please see insert for additional information.**

To kill fleas, flea eggs & larvae, ticks, [and] chewing lice [and mosquitoes], apply [Full or partial brand name] as follows:

- To REMOVE Applicator: Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.
- OPEN Applicator. Hold upright with foil side toward you and snap applicator tip.
- APPLY [Full or partial brand name]. Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the dog's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry. Do not allow your dog to ingest this product. [Do not apply to dogs weighing less than [5 lbs.] [23 lbs.] [45 lbs.] [89 lbs.] or younger than 8 weeks of age.][Do not use two applicators for dogs weighing more than 132 lbs.] Do not use more than one application per dog per month.

[Full or partial brand name] is approved for use on breeding, pregnant, and lactating bitches and puppies as young as 8 weeks.

[Full or partial brand name] remains effective even after bathing, water immersion, or exposure to sunlight.

SIDE EFFECTS: Pets may experience some temporary irritation at the site of application. If signs persist or become more severe within a few days of application, consult a veterinarian immediately.

Frequency of Application

When used monthly, [Full or partial brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations. Do not reapply [Full or partial brand name] for 30 days.

[Full or partial brand name] kills adult fleas, flea eggs, and flea larvae for up to three months. [Full or partial brand name] also prevents development of all flea stages for up to three months. [Full or partial brand name] can control fleas for up to three months, however, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

7/22

(BACK PANEL OF 3X and 6X CARTON) (Cont'd)

[Full or partial brand name] kills ticks for at least one month. A once monthly application is recommended where tick control is needed. [Full or partial brand name] kills all life stages of ticks (larva, nymph and adult). [Full or partial brand name] kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

[Full or partial brand name] kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

[Full or partial brand name] aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

[[Full or partial brand name] kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days, with a monthly application.]



Please call our experts at **1-800-660-1842**, Monday-Friday, 8am-8pm EST, with any questions or comments about flea, tick, chewing lice, [or] sarcoptic mite [or mosquito] control or [Full or partial brand name]



Do not use on cats
pictogram
[1.5 x 1.5 cm]

Keep cats away from treated dogs for 24 hours or until product has dried. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096-4640, USA
MADE IN FRANCE

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Reason to issue: Label Mitigation Changes
EPA Reg. No. 65331-5

Amendment
Date: 7/11/13
Supersedes: 7/2/13

8/22

(TOP OUTER PANEL and LEFT SIDE OUTER PANEL OF 3X and 6X CARTON)

[Full brand name]

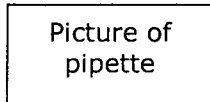
[For use ONLY on DOGS & PUPPIES 8 Weeks or Older and **5-22lbs**]

[For use ONLY on DOGS **23 to 44lbs**]

[For use ONLY on DOGS **45 to 88lbs**]

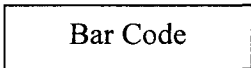
[For use ONLY on DOGS **89 to 132lbs**]

[3][6] doses



(BOTTOM OUTER PANEL OF 3X and 6X CARTON)

For dog use only



(RIGHT SIDE OUTER PANEL OF 3X and 6X CARTON)

EPA Reg. No 65331-5 LOT NO:

EPA Est.

9/22

(INSERT FOR 3X AND 6X)

[Full brand name]

For use ONLY on DOGS & PUPPIES 8 weeks or older and weighing at least [5 lbs. for small dogs] [23 lbs. for medium dogs] [45 lbs. for large dogs] [and] [89 lbs. for extra-large dogs]:

Fast-acting, long-lasting, waterproof treatment and control of fleas, flea eggs & larvae, ticks, chewing lice, [and] sarcoptic mites [and mosquitoes].

ACTIVE INGREDIENTS

fipronil	9.8%
(S)-methoprene.....	8.8%
INERT INGREDIENTS.....	81.4%
TOTAL	100.0%

Do not use on cats pictogram [1.5 x 1.5 cm]

KEEP OUT OF REACH OF CHILDREN

CAUTION

DO NOT USE ON CATS

[Full or partial brand name]:

Fleas

- Kills fleas, flea eggs and flea larvae
- Prevents all flea stages (eggs, larvae, pupae) from developing
- Stops existing infestations and prevents establishment of new infestations
- Kills fleas which may cause flea allergy dermatitis

Ticks

- Kills all life stages of ticks (larva, nymph and adult), including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*),
- Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases

Lice

- Rapidly eliminates chewing lice infestations

Mites

- Aids in the control of sarcoptic mange infestations

[Mosquitoes]

- [Kills mosquitoes]

[Full or partial brand name] is approved for use on all dogs, including:

- Breeding, pregnant, and lactating bitches
- Puppies as young as 8 weeks and weighing at least [5 lbs. for small dogs] [23 lbs. for medium dogs] [45 lbs. for large dogs][and] [89 lbs. for extra-large dogs]

One spot application is all that's needed:

[Full or partial brand name] spreads from the single point of application, rapidly covering the entire dog and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing [Full or partial brand name] onto the skin and hair coat, so it keeps working even if the dog gets wet.

Fleas, ticks, and chewing lice are killed quickly after coming into contact with a treated dog.

Fleas and ticks do not need to bite the dog in order to die.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET,

10/22

(INSERT FOR 3X AND 6X) (Cont'd)

READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

To kill fleas, flea eggs & larva, ticks, [and] chewing lice [and mosquitoes] apply [Full or partial brand name] as follows:

- To **REMOVE** Applicator: Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.

- **OPEN** Applicator

Hold upright with foil side toward you and snap applicator tip.

- **APPLY** [Full or partial brand name]

Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the dog's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry. Do not allow your dog to ingest this product. [Do not apply to dogs weighing less than [5 lbs. for small dogs] [23 lbs. for medium dogs] [45 lbs. for large dogs] [89 lbs. for extra-large dogs] or younger than 8 weeks of age.][Do not use two applicators for dogs weighing more than 132 lbs.] Do not use more than one application per dog per month.

[Full or partial brand name] is approved for use on all dogs, including breeding, pregnant, and lactating bitches and puppies as young as 8 weeks.

[Full or partial brand name] remains effective even after bathing, water immersion, or exposure to sunlight.

FREQUENCY OF APPLICATION

When used monthly, [Full or partial brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations. Do not reapply [Full or partial brand name] for 30 days.

[Full or partial brand name] kills adult fleas, flea eggs, and flea larvae for up to three months.

[Full or partial brand name] also prevents development of all flea stages for up to three months. [Full or partial brand name] can control fleas for up to three months, however, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

[Full or partial brand name] kills ticks for at least one month. A once monthly application is recommended where tick control is needed.

[Full or partial brand name] kills all life stages of ticks (larva, nymph and adult). [Full or partial brand name] kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

[Full or partial brand name] kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

[Full or partial brand name] aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

[[Full or partial brand name] kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days, with a monthly application.]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE. Store unused product in original container, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor

(INSERT FOR 3X AND 6X) (Cont'd)

or outdoor drain.

CONTAINER DISPOSAL. If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age and [5 lbs. for small dogs] [23 lbs. for medium dogs] [45 lbs. for large dogs] [and] [89 lbs. for extra-large dogs]. Individual sensitivities, while rare, may occur after using any pesticide product.

SIDE EFFECTS: Pets may experience some temporary irritation at the site of application. If signs persist or become more severe within a few days of application, consult a veterinarian immediately.

If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-660-1842, Monday-Friday, 8am-8pm EST.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

HOW SUPPLIED

For easy and convenient treatment, [Full or partial brand name] is available in sizes for use ONLY on small dogs and puppies 8 weeks or older and 5 - 22 lbs., medium dogs ONLY 23-44 lbs., large dogs ONLY 45-88 lbs., and extra-large dogs ONLY 89-132 lbs.

WARRANTY

To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions.

Reason to issue: Label Mitigation Changes
EPA Reg. No. 65331-5

Amendment
Date: 7/11/13
Supersedes: 7/2/13

12/
22

(INSERT FOR 3X AND 6X) (Cont'd)

Merial Limited

3239 Satellite Blvd.

Duluth, GA 30096-4640, USA

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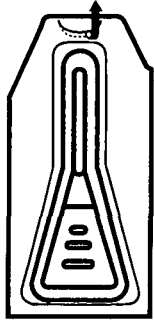
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Bar code

13/
22

(3X and 6X BLISTER)

[Full or partial brand name]



TO REMOVE APPLICATOR:

Lift and remove the plastic tab to expose foil backing;
then peel away the foil. Or use scissors to open.

[0.023 fl oz][0.045 fl oz][0.091 fl oz][0.136 fl oz]
Lot #

[ONLY for DOGS & PUPPIES 8 Weeks and Older and 5-22 lbs]
[ONLY for DOGS 23-44 lbs]
[ONLY for DOGS 45-88 lbs]
[ONLY for DOGS 89-132 lbs]

Reason to issue: Label Mitigation Changes
EPA Reg. No. 65331-5

Amendment
Date: 7/11/13
Supersedes: 7/2/13

14/
22

(1X, 3X, 6X PIPETTE)

MERIAL
Contains fipronil (9.8%)
(S)-methoprene (8.8%)

Do not use on
cats pictogram

[ONLY for DOGS & PUPPIES 8 Weeks and Older and 5-22 lbs]
[ONLY for DOGS 23-44 lbs]
[ONLY for DOGS 45-88 lbs]
[ONLY for DOGS 89-132 lbs]



[0.023 fl oz][0.045 fl oz][0.091 fl oz][0.136 fl oz]
[Full or partial brand name]

Keep out of reach of children
See full label for additional directions

CAUTION
EPA Reg. No. 65331-5

15/22

Reason to issue: Label Mitigation Changes
EPA Reg. No. 65331-5

Amendment
Date: 7/11/13
Supersedes: 7/2/13

(3X AND 6X COMPLIANCE CARD - FRONT)

FRONTLINE®

See other side for more...



Fleas



Ticks



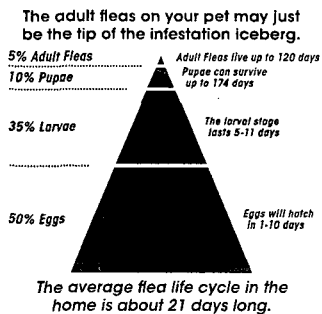
Chewing Lice

Some tips and other information

- To successfully control fleas and ticks, all dogs and cats must be treated with their own dose of FRONTLINE®.
- Apply according to label instructions, ensuring the product is applied to the skin, not on top of the fur and not near the collar. It may be helpful to remove the collar before application, so it doesn't absorb the product.
- Remember, your pet needs to be dry at the time FRONTLINE is applied and remain dry 24 hours after application.
- Verify pipette is empty after application (multiple squeezes may be necessary to apply the entire dose).
- Even indoor pets need flea and tick control because you or other pets in the household may bring fleas into the home. These fleas can lead to a flea infestation.

FLEAS: What you need to know

It can take up to 3 months to get rid of a serious flea infestation because of all of the flea life stages that existed BEFORE you started using FRONTLINE.



16/22

(3X AND 6X COMPLIANCE CARD - BACK)

Calendar Reminder Stickers

To ensure continued protection of your pets, use these stickers as a reminder to apply and re-purchase FRONTLINE.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply FRONTLINE monthly.

Don't forget to re-purchase!

QUESTIONS?

Contact your veterinarian or call our technical experts at **1-800-660-1842**.
Monday-Friday, 8am-8pm. For more information, visit **www.FRONTLINE.com**.

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6 Months
use all 6 stickers

3 stickers that read "Apply FRONTLINE®"
with a picture of a pipette

3 Months

3 stickers that read "Apply FRONTLINE®"
with a picture of a pipette

Bar code

17/22

Reason to issue: Label Mitigation Changes
EPA Reg. No. 65331-5

Amendment
Date: 7/11/13
Supersedes: 7/2/13

(FRONT PANEL OF 1X Insert)

(Note: font size of **FOR DOGS** will be 40% of the size of the largest letter in the brand name on the front panel)



[Full brand name]

EPA Reg. No. 65331-5
EPA Est. No. 65331-FR-2
MADE IN FRANCE

Picture of Dog

Kills fleas, ticks, [&] chewing lice [& mosquitoes]

- Fast-acting
- Long-lasting
- Waterproof

ACTIVE INGREDIENTS:

Fipronil.....9.8%
 (S)-methoprene.....8.8%
 INERT INGREDIENTS.....81.4%
 TOTAL100%

Do not use on cats pictogram

Net Contents :

- [1-0.023 fl oz (0.67 ml) applicator]
- [1-0.045 fl oz (1.34 ml) applicator]
- [1-0.091 fl oz (2.68 ml) applicator]
- [1-0.136 fl oz (4.02 ml) applicator]

DO NOT USE ON CATS

1 monthly dose

Kills ticks, including those that may transmit Lyme disease

Bar code

[For use ONLY on DOGS & PUPPIES 8 Weeks or Older and **5-22lbs**]
 [For use ONLY on DOGS **23 to 44lbs**]
 [For use ONLY on DOGS **45 to 88lbs**]
 [For use ONLY on DOGS **89 to 132lbs**]

See inside panels for FIRST AID and PRECAUTIONARY statements.
KEEP OUT OF REACH OF CHILDREN

CAUTION

(INNER PANELS FOR 1X INSERT)

[Full brand name]

For use ONLY on DOGS & PUPPIES 8 weeks or older and weighing at least [5 lbs.][23 lbs] [45 lbs.] [89 lbs.]:

Fast-acting, long-lasting, waterproof treatment and control of fleas, flea eggs & larvae, ticks, chewing lice, [and] sarcoptic mites [and mosquitoes].

ACTIVE INGREDIENTS

fipronil	9.8%
(S)-methoprene.....	8.8%
INERT INGREDIENTS.....	81.4%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[Full or partial brand name]:

Fleas

- Kills fleas, flea eggs and flea larvae
- Prevents all flea stages (eggs, larvae, pupae) from developing
- Stops existing infestations and prevents establishment of new infestations
- Kills fleas which may cause flea allergy dermatitis

Ticks

- Kills all life stages of ticks (larva, nymph and adult), including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*),
- Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis, and other tick-borne diseases

Lice

- Rapidly eliminates chewing lice infestations

Mites

- Aids in the control of sarcoptic mange infestations

[Mosquitoes]

- [Kills mosquitoes]

[Full or partial brand name] is approved for use on all dogs, including:

- Breeding, pregnant, and lactating bitches
- Puppies as young as 8 weeks and weighing at least [5 lbs.] [23lbs.] [45 lbs.] [89 lbs.]

One spot application is all that's needed:

[Full or partial brand name] spreads from the single point of application, rapidly covering the entire dog and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing [Full or partial brand name] onto the skin and hair coat, so it keeps working even if the dog gets wet.

Fleas, ticks, and chewing lice are killed quickly after coming into contact with a treated dog. Fleas and ticks do not need to bite the dog in order to die.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

(INNER PANELS FOR 1X INSERT) (Cont'd)

To kill fleas, flea eggs & larva, ticks, [and] chewing lice [and mosquitoes] apply [Full or partial brand name] as follows:

- **OPEN** Applicator

Hold upright with foil side toward you and snap applicator tip.

- **APPLY** [Full or partial brand name]

Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the dog's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry. Do not allow your dog to ingest this product. [Do not use on dogs weighing less than [5 lbs.] [23lbs.] [45 lbs.] [89 lbs.] or younger than 8 weeks of age.][Do not use two applicators for dogs weighing more than 132 lbs.] Do not use more than one application per dog per month. [Full or partial brand name] is approved for use on all dogs, including breeding, pregnant, and lactating bitches and puppies as young as 8 weeks.

[Full or partial brand name] remains effective even after bathing, water immersion, or exposure to sunlight.

FREQUENCY OF APPLICATION

When used monthly, [Full or partial brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations. Do not reapply [Full or partial brand name] for 30 days.

[Full or partial brand name] kills adult fleas, flea eggs, and flea larvae for up to three months.

[Full or partial brand name] also prevents development of all flea stages for up to three months. [Full or partial brand name] can control fleas for up to three months, however, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

[Full or partial brand name] kills ticks for at least one month. A once monthly application is recommended where tick control is needed.

[Full or partial brand name] kills all life stages of ticks (larva, nymph and adult). [Full or partial brand name] kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

[Full or partial brand name] kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

[Full or partial brand name] aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

[[Full or partial brand name] kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days, with a monthly application.]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE. Store unused product in original container, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

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(INNER PANELS FOR 1X INSERT) (Cont'd)

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age and [5 lbs.] [23lbs.] [45 lbs.] [89 lbs.]. Individual sensitivities, while rare, may occur after using any pesticide product.

SIDE EFFECTS: Pets may experience some temporary irritation at the site of application. If signs persist or become more severe within a few days of application, consult a veterinarian immediately.

If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-660-1842, Monday-Friday, 8am-8pm EST.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

HOW SUPPLIED

For easy and convenient treatment, [Full or partial brand name] is available in sizes for use ONLY on small dogs and puppies 8 weeks or older and 5-22 lbs., medium dogs ONLY 23-44 lbs., large dogs ONLY 45-88 lbs., and extra-large dogs ONLY 89-132 lbs.

WARRANTY

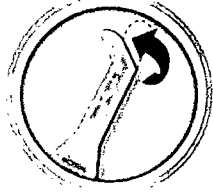
To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions.

Merial Limited

3239 Satellite Blvd.
Duluth, GA 30096-4640, USA
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(BACK PANEL OF 1X Insert)

How to Apply [Full or partial brand name]



**Step 1.
OPEN Applicator**

Hold upright with foil side toward you and snap applicator tip.



**Step 2.
APPLY [Full or partial brand name]**

Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the dog's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry. Do not allow your dog to ingest this product. [Do not apply to dogs weighing less than [5 lbs.] [23lbs.] [45 lbs.] [89 lbs.] or younger than 8 weeks of age.][Do not use two applicators for dogs weighing more than 132 lbs.] Do not use more than one application per dog per month.

Questions or Comments?

Call: 1-800-660-1842.

**Monday-Friday, 8am-8pm EST or
visit us at [www. FRONTLINE.com](http://www.FRONTLINE.com)**

Bar code

Reason to issue: Label Mitigation Changes
EPA Reg. No. 65331-5

Amendment
Date: 7/11/13
Supersedes: 7/2/13

22/
/22

(1X BLISTER)

