

65331-4

3/9/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 09, 2010

Karen Cunningham, DVM
Head, Regulatory Affairs LCM
Merial, Ltd.
3239 Satellite Blvd., Bld. 500
Duluth, GA 30096

Subject: Revised Child Resistant (CR) Packaging Wording

Frontline Top Spot for Cats: EPA Reg. No. 65331-2
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

Submissions dated August 14 and December 11, 2009

Dear Dr. Cunningham:

The above referenced submissions, in connection with registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

Please note that we have approved the amended labeling for each product, with the understanding that it is consistent with the Agency's previously stamped accepted labels. See enclosed copies of the stamped labels for your record. If you have any questions concerning this action please contact Dr. B.A. Akinlosotu at (703) 605-0653.

Sincerely,

Richard Gebken,
Product Manager 10
Insecticide Branch
Registration Division (7505P)

Enclosure

Monkui Copy for file

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ACCEPTED

MAR 09 2010

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 65331-4

FRONTLINE®

Plus
for cats

For Cats & Kittens
8 weeks or older.

3(6)
Applicators

FRONTLINE®

3(6)
Applicators

Kills fleas, flea eggs, ticks, chewing lice
& mosquitoes

- Fast-acting
- Kills ticks including those that may transmit Lyme disease
- Waterproof

For Cats & Kittens
8 weeks or older.

ACTIVE INGREDIENTS	
fipronil.....	9.8%
(S)-methoprene.....	11.8%
INERT INGREDIENTS.....78.4%	
TOTAL.....	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

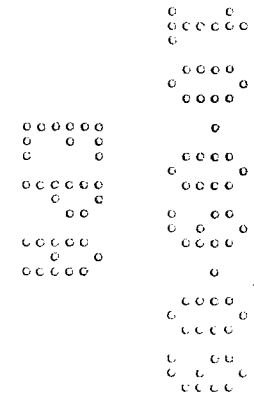
Contains 3 (6)-0.017 fl oz
(0.50 ml) applicators

Plus
for cats

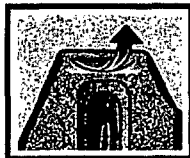
Lift Here To Open



(Prototype Graphics)

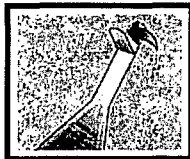


How to Apply **FRONTLINE[®]** *Plus* for cats



1. Remove Applicator

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



2. Open Applicator

Hold upright and snap applicator tip away from face and body.

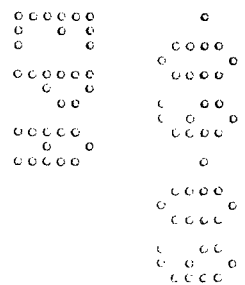


3. Apply **FRONTLINE[®] PLUS FOR CATS**

Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin.

INSERT COVER TAB HERE

Questions or Comments?
Call: 1-800-660-1842



FRONTLINE[®] *Plus* for cats

FRONTLINE PLUS FOR CATS provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes for cats and kittens 8 weeks or older.

- **Stops and prevents infestations**
- **Kills adult fleas, flea eggs & flea larvae**
- **Prevents all flea stages (eggs, larvae, pupae) from developing**
- **Kills fleas which may cause flea allergy dermatitis**
- **Kills all stages of deer ticks (which may carry Lyme disease), brown dog ticks, American dog ticks & lone star ticks**
- **Kills mosquitoes**
- **Prevents and controls reinfestations**
- **Rapidly eliminates infestations with chewing lice**
- **Can also be used on breeding, pregnant and lactating queens**
- **Fast-acting**
- **Long-lasting**
- **Waterproof**
- **Convenient to use**

FRONTLINE PLUS FOR CATS contains fipronil and the insect growth regulator (IGR) (S)-methoprene. FRONTLINE PLUS effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.



Flea Adult



Flea Eggs



Flea Larvae



Flea Pupae



Brown Dog Tick



Lone Star Tick



Deer Tick



American Dog Tick

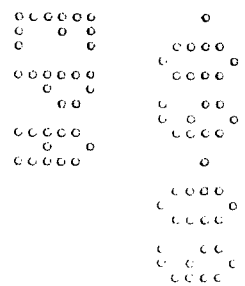


Chewing Lice



Mosquito

XXXXXX
036





3 (6) Applicators
For Cats & Kittens 8 weeks or older

FRONTLINE[®] Plus for cats

FRONTLINE[®] Plus for cats

FRONTLINE PLUS FOR CATS provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes for cats and kittens 8 weeks or older.

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 CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.**

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, deer ticks (which may carry Lyme disease), chewing lice and mosquitoes, apply to cats and kittens (8 weeks or older) as follows: Remove applicator from child-resistant package. Hold applicator upright and snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one applicator per treatment is needed.

FRONTLINE PLUS FOR CATS can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

Frequency Of Application

When used monthly, FRONTLINE PLUS FOR CATS completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that FRONTLINE PLUS kills adult fleas, flea eggs, and flea larvae for up to six weeks. FRONTLINE PLUS also prevents development of all flea stages for up to six weeks. FRONTLINE PLUS kills ticks for at least one month. A once monthly application is recommended where tick and mosquito control is needed. Although FRONTLINE PLUS can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of FRONTLINE PLUS FOR CATS kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

FRONTLINE PLUS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply FRONTLINE PLUS for 30 days.

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096-4640, USA
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EPA Reg. No. 65331-4
EPA Est. 65331-FR-2
(EPA Est. 65331-DEU-1)
(EPA Est. 65331-GA-1)
(EPA Est. 74528-CHE-1)

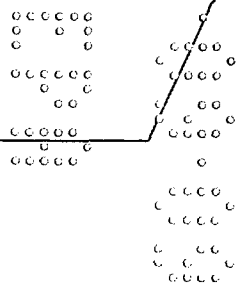


Please call our experts at 1-800-660-1842 if you have any questions or comments about flea, tick, lice and mosquito control or FRONTLINE PLUS.



LOT NO :

For animal use only



CATS compliance card x3 - Front

FRONTLINE®

"Flea, Tick, Chewing Lice and Mosquito Protection Card"

Plus for cats

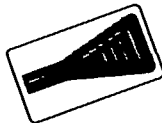
Apply FRONTLINE® PLUS FOR CATS monthly, or as needed, for continuous protection against fleas, ticks, chewing lice and mosquitoes.

Pet's Name:

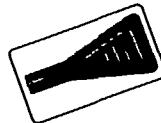
Date of first treatment:



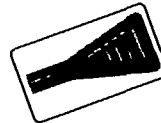
Month 1



Month 2



Month 3



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Place stickers on calendar as a reminder to apply FRONTLINE® PLUS FOR CATS.

037 XXXXXX

(Prototype Graphics)

CATS compliance card x3 - Back

Remove the adhesive backing and attach to your refrigerator door

Fleas, Ticks, Chewing Lice and Mosquitoes can be a year-round problem!

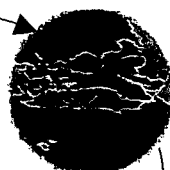
Spring

Fleas and ticks breed more frequently as spring progresses.



Summer

The period of highest risk. Summer temperatures and humidity can quickly lead to flea and tick infestations.



Winter

Minimize the risk of any reinfestation.



Autumn

The risk continues. Fleas and ticks (brown dog ticks, American dog ticks, lone star ticks, and deer ticks which may carry Lyme disease) remain a threat.

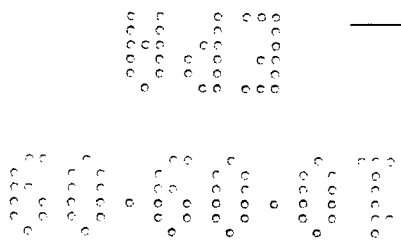
Flea, Tick, Chewing Lice and Mosquito Protection Card Instructions for Use

The calendar stickers on the front of this card will help you remember to apply FRONTLINE[®] PLUS FOR CATS.

- 1 - Write the date of your pet's first treatment in the box shown.
- 2 - After treating your pet, peel off the sticker corresponding to the current month.
- 3 - Place the remaining stickers on your calendar as a reminder to apply FRONTLINE[®] PLUS FOR CATS monthly or as needed.



(Prototype Graphics)



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CATS compliance card x6 - Front

FRONTLINE® *Plus* for cats

"Flea, Tick, Chewing Lice and Mosquito Protection Card"

Apply FRONTLINE® PLUS FOR CATS monthly, or as needed, for continuous protection against fleas, ticks, chewing lice and mosquitoes.

Pet's Name:

Date of first treatment:



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Month 1	Month 2	Month 3
Month 4	Month 5	Month 6

Place stickers on calendar as a reminder to apply FRONTLINE® PLUS FOR CATS.

017 XXXXXX

(Prototype Graphics)

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CATS compliance card x6 - Back

Remove the adhesive backing and attach to your refrigerator door

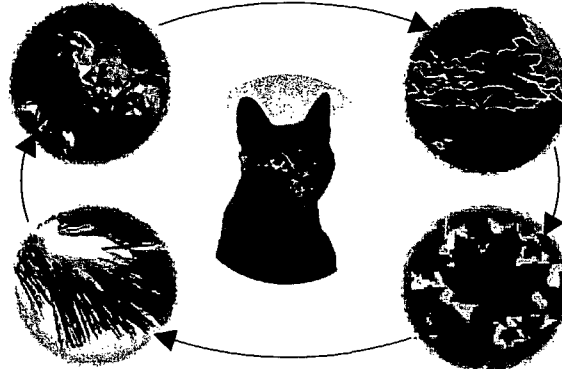
Fleas, Ticks, Chewing Lice and Mosquitoes can be a year-round problem!

Spring

Fleas and ticks breed more frequently as spring progresses.

Summer

The period of highest risk. Summer temperatures and humidity can quickly lead to flea and tick infestations.



Winter

Minimize the risk of any reinfestation.

Autumn

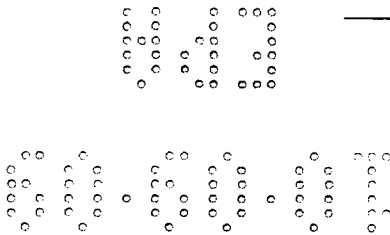
The risk continues. Fleas and ticks (brown dog ticks, American dog ticks, lone star ticks, and deer ticks which may carry Lyme disease) remain a threat.

Flea, Tick, Chewing Lice and Mosquito Protection Card Instructions for Use

The calendar stickers on the front of this card will help you remember to apply FRONTLINE® PLUS FOR CATS.
 1 - Write the date of your pet's first treatment in the box shown.
 2 - After treating your pet, peel off the sticker corresponding to the current month.
 3 - Place the remaining stickers on your calendar as a reminder to apply FRONTLINE® PLUS FOR CATS monthly or as needed.



(Prototype Graphics)



FRONTLINE®

Plus

for cats

FOR CATS & KITTENS 8 weeks or older
Convenient spot treatment for fast-acting,
long-lasting control of fleas, ticks, chewing lice and
mosquitoes.

ACTIVE INGREDIENTS

fipronil:	9.8%
(S)-methoprene	11.8%
INERT INGREDIENTS	78.4%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

FRONTLINE® PLUS FOR CATS provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes for cats and kittens.

- Stops and prevents infestations
- Kills adult fleas, flea eggs, and flea larvae
- Prevents all flea stages (eggs, larvae, pupae) from developing
- Kills fleas which may cause flea allergy dermatitis
- Kills all stages of deer ticks (which may carry Lyme disease), brown dog ticks, American dog ticks, and lone star ticks
- Kills mosquitoes
- Prevents and controls reinfestations
- Rapidly eliminates infestations with chewing lice
- Can also be used on breeding, pregnant and lactating queens
- Fast-acting
- Long-lasting
- Waterproof
- Convenient to use

FRONTLINE® PLUS FOR CATS contains fipronil and the insect growth regulator (IGR) (S)-methoprene. FRONTLINE® PLUS effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

DIRECTIONS FOR USE

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Remove applicator from child-resistant package. Hold applicator upright and snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one applicator per treatment is needed.



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FRONTLINE PLUS FOR CATS can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, FRONTLINE® PLUS FOR CATS completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that FRONTLINE® PLUS kills adult fleas, flea eggs, and flea larvae for up to six weeks. FRONTLINE® PLUS also prevents development of all flea stages for up to six weeks. FRONTLINE® PLUS kills ticks for at least one month. A once monthly application is recommended where tick control is needed. Although FRONTLINE® PLUS can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of FRONTLINE PLUS® FOR CATS kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

FRONTLINE® PLUS FOR CATS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply FRONTLINE® PLUS for 30 days.

STORAGE AND DISPOSAL

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

STORAGE. Store unused product in original container only, 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: Do not reuse 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: Flush eyes with plenty of water. Call a doctor if irritation persists.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-660-1842 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

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

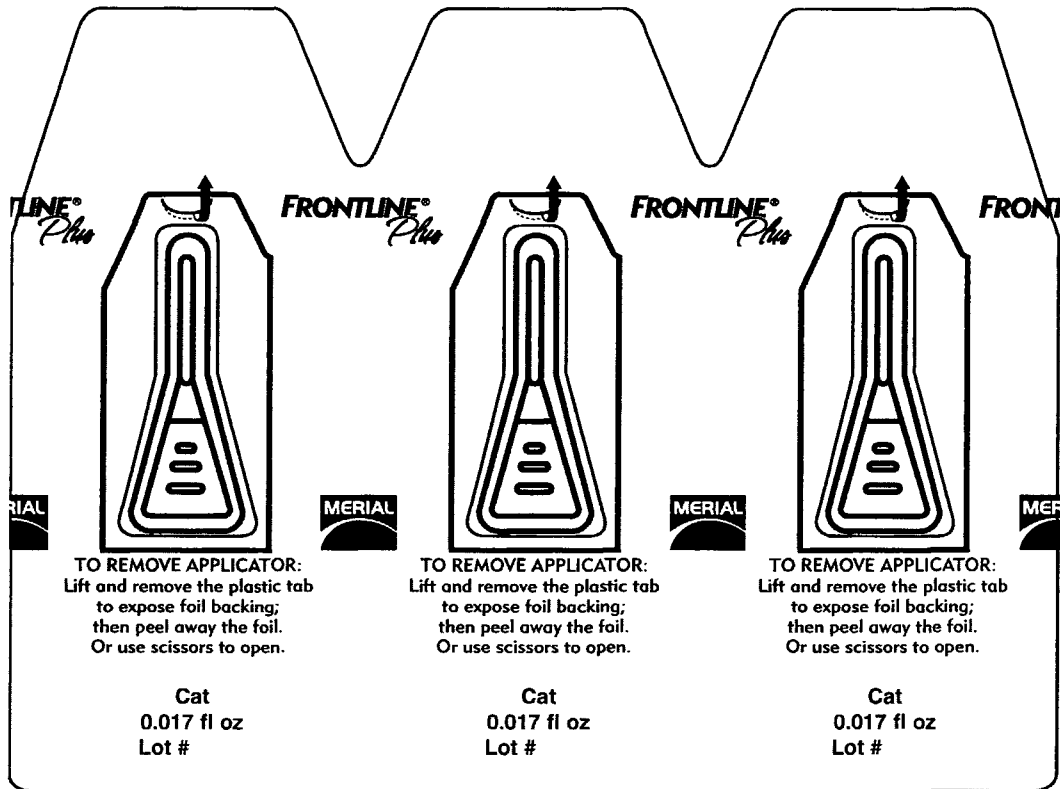
WARRANTY

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. EPA Reg. No. 65331-4

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 Duluth, GA 30096-4640, USA

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