

65331-4

06/21/2001

1/12

JUN 21 2001

Zareen Ahmed, Ph.D.
Merial
3239 Satellite Blvd.
Duluth, GA 30096-4640

Dear Dr. Ahmed:

Subject: Frontline Plus for Cats
EPA Reg. No. 65331-4
Letter dated 5/24/01

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

In accordance with PR Notice 2001-1, you are strongly urged to change the skin and eye First Aid Statements to read as follows:

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 advice.

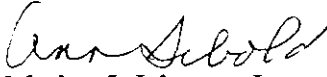
If in eyes:

- 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.

Alternately, you may delete the skin and eye first aid statements.

If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,

for 
Marion J. Johnson, Jr.
Product Manager 3
Insecticide Branch
Registration Division (7505C)

ACCEPTED
with COMMENTS

JUN 21 2001

65331-4

Master Label
Carton

FRONTLINE®
Plus for cats
For Cats & Kittens
8 weeks or older
3 (6)
Applicators

FRONTLINE®



Kills fleas, flea eggs & ticks

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

For Cats & Kittens
8 weeks or older

Plus
for cats

Lift Here To Open

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

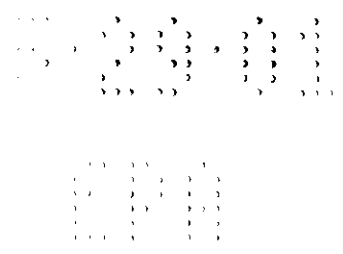
**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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

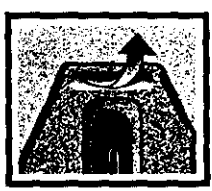


(PROTOTYPE GRAPHICS)

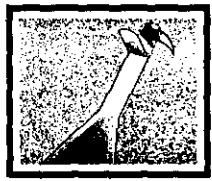
Printed at 110%
Actual Size



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



1. Remove Applicator from Child-Resistant Package
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.



2. Open Applicator
Hold upright and snap applicator tip away from face and body.

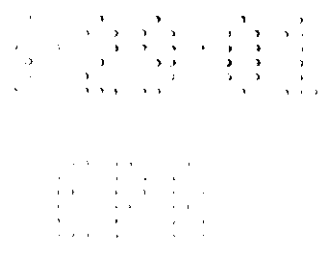


3. Apply FRONTLINE PLUS FOR CATS
Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin.

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 and ticks 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**
- **Prevents and controls reinfestations**
- **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 and ticks.



Adult Flea



Flea Eggs



Flea Larvae



Flea Pupae



Brown Dog Tick



Lone Star Tick



Deer Tick



American Dog Tick

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

FRONTLINE[®] Plus for cats

3 (6) Applicators

FRONTLINE[®] Plus for cats

FRONTLINE PLUS FOR CATS provides fast, effective and convenient treatment and control of fleas and ticks 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 and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease), 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.

Frequency Of Application

When used monthly, FRONTLINE PLUS FOR CATS completely breaks the flea life cycle and controls tick 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.

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

MADE IN FRANCE

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EPA Reg. No. 65331-4
EPA Est. 65331-FR-2
(EPA Est. 65331-DEU-1)



If you are not satisfied with FRONTLINE PLUS for any reason, the product will be replaced or the purchase price refunded. If you have any questions or comments, please call 1-800-660-1842.

LOT NO:

For animal use only

FRONT

BACK

FRONTLINE® Plus for cats

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

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 and ticks 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 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
- Prevents and controls reinfestations
- 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 and ticks.

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

To kill fleas and all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (which may carry Lyme disease), apply to cats or 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.

FREQUENCY OF APPLICATION

When used monthly, FRONTLINE PLUS FOR CATS completely breaks the flea life cycle and controls tick 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.

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. Waste resulting from use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL. Securely wrap original container in several layers of newspaper and discard in trash.

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, aged, pregnant, or nursing 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

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

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FRONTLINE

PLUS

FRONTLINE[®] for cats *Plus* "Flea and Tick Protection Card"

For Cats & Kittens 8 weeks or older.

Apply FRONTLINE[®] PLUS FOR CATS monthly, or as needed, for continuous protection against fleas and ticks.

Pet's Name: _____

Date of first treatment: _____



Month 1



Month 2



Month 3



Place stickers on calendar as a reminder to apply FRONTLINE[®] PLUS FOR CATS.
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XXXXX|FPO|XXXX

(Prototype Graphics)

Remove the adhesive backing and attach to your refrigerator door.

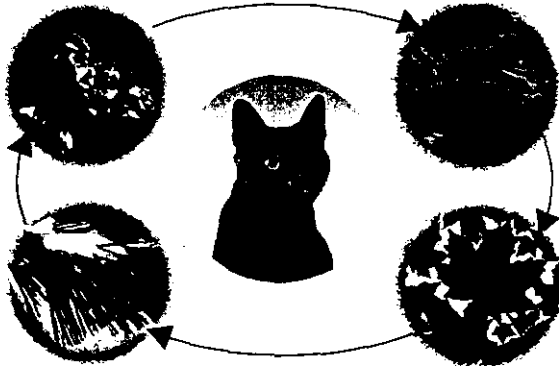
Fleas and ticks can be a year-round problem!

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 and Tick Protection Card
Instructions for Use
 The calendar stickers on the front of this card will help you remember to apply FRONTLINE PLUS FOR CATS every month of the year. Treatment is the key to keeping your pet free of fleas and ticks. Place the sticker corresponding to the current month on your calendar as a reminder to apply FRONTLINE PLUS FOR CATS monthly or as directed.



(Prototype Graphics)

FRONTLINE

Plus

FRONTLINE[®] for cats

For Cats & Kittens 8 weeks or older.

"Flea and Tick Protection Card"







Plus

Apply FRONTLINE[®] PLUS FOR CATS monthly, or as needed, for continuous protection against fleas and ticks.

Pet's Name:

Date of first treatment:

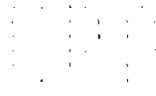


Month 1 	Month 2 	Month 3 
Month 4 	Month 5 	Month 6 

Place stickers on calendar as a reminder to apply FRONTLINE[®] PLUS FOR CATS.
©FRONTLINE is a registered trademark of Merial. ©2001 Merial. All rights reserved.

xxx-xxx-FPO-xxx

(Prototype Graphics)



Remove the adhesive backing and attach to your refrigerator door.

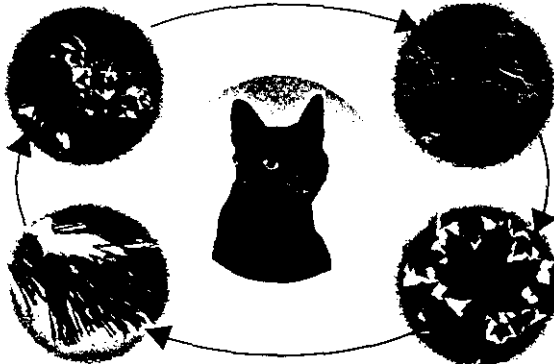
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Flea and Tick Protection Card Instructions for Use

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

Apply FRONTLINE PLUS FOR CATS monthly to your pet. The tickers correspond to the calendar. Use the Tickering Ticker Year Calendar as a reminder to apply FRONTLINE PLUS FOR CATS monthly to your pet.

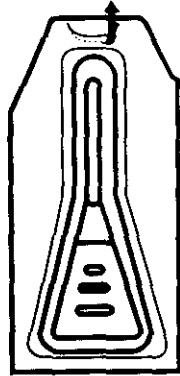


(Prototype Graphics)

FRONTLINE

Plus

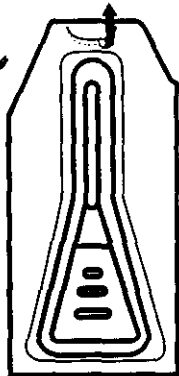
FRONTLINE[®]
Plus



TO REMOVE APPLICATOR:
Use scissors. Or lift and remove
plastic tab to expose foil,
then peel down.

Cat
0.017 fl oz
Lot #

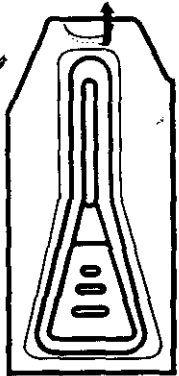
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FRONTLINE[®]
Plus



12/12

