

65331-2

06/15/2001

1/11

JUN 15 2001

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

Dear Dr. Ahmed:

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

Change the 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.

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

Sincerely,

for Ann Sibold

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

2/11

Master Label
Carton

FRONTLINE®

Kills fleas & ticks

Top Spot®
for cats

Convenient spot treatment for
fast-acting, long-lasting
control of fleas and ticks

For Cats & Kittens

ACTIVE INGREDIENTS	
fipronil	9.7%
INERT INGREDIENTS	90.3%
TOTAL	100.0%

**KEEP OUT OF
REACH OF CHILDREN
CAUTION**

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



3 (6)

Lift Here To Open



FRONTLINE®
Top Spot®
for cats

For Cats & Kittens

3 (6)
Applicators

(PROTOTYPE GRAPHICS)

ACCEPTED
with COMMENTS
to EPA Master List

JUN 15 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, this product is
registered under EPA Reg. No.

65331-2

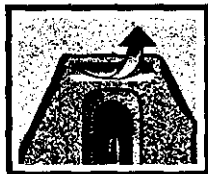
Printed at 110%
Actual Size

FRONTLINE

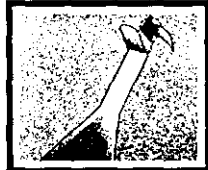
Top Spot

How to Apply

FRONTLINE[®] Top Spot[®] for cats



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



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



3. To Apply FRONTLINE
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® For Cats & Kittens

Top Spot® for cats

FRONTLINE provides convenient and effective flea and tick control for cats and kittens.

- **Fast-acting and long-lasting**
- **Prevents reinfestation**
- **Convenient to use**
- **Kills newly emerged adult fleas before they lay eggs**
- **Controls fleas which may cause flea allergy dermatitis**
- **Kills all stages of brown dog ticks, American dog ticks, lone star ticks and deer ticks (which may carry Lyme disease)**

FRONTLINE contains the active ingredient fipronil which has a unique mode of action that effectively targets fleas and ticks. 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.



Adult Flea



Brown Dog Tick



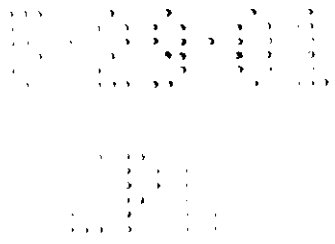
Lone Star Tick



Deer Tick



American Dog Tick



FRONTLINE

"Flea and Tick Protection Card"

Top Spot

for cats

Apply FRONTLINE® 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®
®FRONTLINE is a registered trademark of Merial. ©2001 Merial. All rights reserved.

XXXXEPCXXXX

(Prototype Graphics)

Remove the adhesive backing and attach to your refrigerator door.

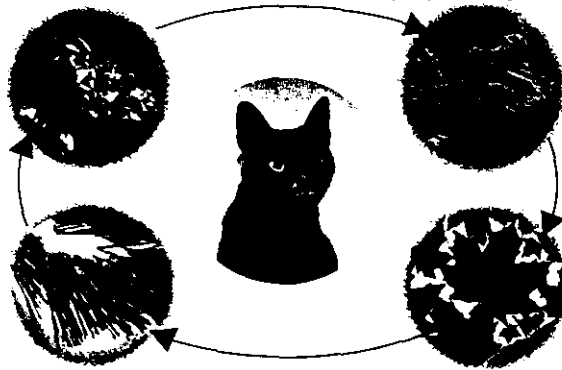
Fleas and ticks can be a year-round problem!

Spring

Prevention
Fleas and ticks start to breed more quickly as spring progresses.

Summer

Prevention - Treatment
The period of highest risk. Summer temperatures and humidity can quickly lead to huge infestations.



Winter

Prevention
The risk is still there. With the cold weather, fleas can breed in your warm home.

Autumn

Prevention - Treatment
Prevents reinfestation from newly emerged adult fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease).

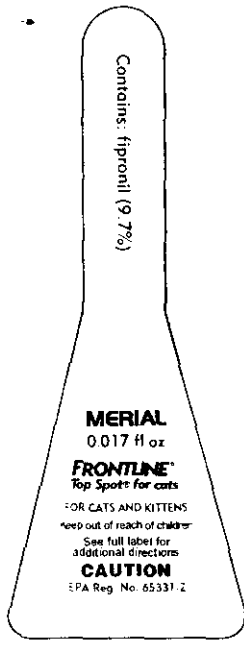
Flea and Tick Protection Card
Instructions for Use

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

- 1- Write the date of your pet's first treatment in the box above.
- 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 monthly or as needed.



(Prototype Graphics)



Contains: fipronil (9.7%)

Merial
0.017 fl oz

FRONTLINE
Top Spot for cats

FOR CATS AND KITTENS
keep out of reach of children

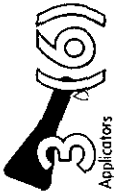
See full label for
additional directions

CAUTION
EPA Reg. No. 65331-2

8/11

For Cats & Kittens
3 (6) Applicators

FRONTLINE
Top Spot[®]
for cats



FRONTLINE[®]

Top Spot[®]
for cats



FRONTLINE provides convenient and effective flea and tick control for cats and kittens.

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 or kittens (12 weeks or older) as follows:

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 TOP SPOT FOR CATS completely controls both flea and tick infestations. Research demonstrates that FRONTLINE kills adult fleas for up to six weeks. FRONTLINE kills ticks for at least one month. A once monthly application is recommended where tick control is needed. Although FRONTLINE 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 remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply FRONTLINE for 30 days.

If you are not satisfied with FRONTLINE 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:

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

MADE IN FRANCE

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



For animal use only

FRONTLINE[®]

Top Spot[®]
for cats

FOR CATS & KITTENS

Convenient spot treatment for fast-acting, long-lasting control of fleas and ticks.

ACTIVE INGREDIENT

fipronil	9.7%
INERT INGREDIENTS	90.3%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

FRONTLINE provides convenient and effective flea and tick control for cats and kittens.

- Fast-acting and long-lasting
- Prevents reinfestation
- Convenient to use
- Kills newly emerged adult fleas before they lay eggs
- Controls fleas which may cause flea allergy dermatitis
- Kills all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)

FRONTLINE contains the active ingredient fipronil which has a unique mode of action that effectively targets fleas and ticks. 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.

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 (12 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 TOP SPOT FOR CATS completely controls both flea and tick infestations. Research demonstrates that FRONTLINE kills adult fleas for up to six weeks. FRONTLINE kills ticks for at least one month. A once monthly application is recommended where tick control is needed. Although FRONTLINE 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 remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply FRONTLINE 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: 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: 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 12 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product for pets. 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 animals. Consult a veterinarian before using this product with other pesticides. This product may be harmful to debilitated, aged, pregnant, or nursing animals; consult a veterinarian before using. Call 1-800-660-1842 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE. Keep away from heat and 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. 65331-2

Merial Limited

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

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FRONTLINE

Top Spot

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"Flea and Tick Protection Card"

Top Spot
for cats

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Pet's Name:

Date of first treatment:



Month 1

Month 2

Month 3



Place stickers on calendar as a reminder to apply FRONTLINE®

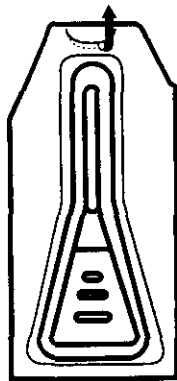
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MAX 2X FPO MAX

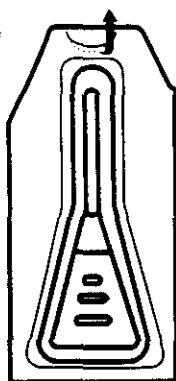
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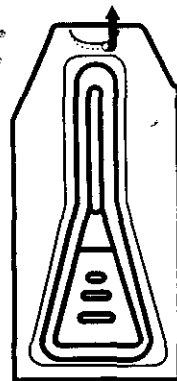
FRONTLINE[®]
Top Spot[®]



FRONTLINE[®]
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Top Spot[®]



FRONTLINE[®]
Top Spot[®]



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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