

65331-2

02/14/2003

1/12



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

FEB 14 2003

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Timothy Dotson  
Merial  
3239 Satellite Blvd.  
Duluth, Ga. 30096

Dear Mr. Dotson:

Subject: Frontline Top Spot for Cats  
EPA Reg. No. 65331-2  
Submission dated 5/9/02

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.

Update the disposal statements in accordance with PR Notice 2001-6.

You are strongly urged, but not required, to revise the first aid statements to conform to PR Notice 2001-1.

Efficacy reviews are enclosed. Notwithstanding some of the reviewer's conclusions regarding flea allergy dermatitis, the Agency does not have authority to approve medical claims. If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,

*Ann Sibold*

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

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
FEB 14 2003

Under the FIFRA Act, as amended, for the pesticide  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide,  
registered under EPA Reg. No.  
65331-2

**FRONTLINE**  
Top Spot®  
for cats

For Cats & Kittens  
8 weeks or older.

3(6)  
Applicators

# FRONTLINE®

Kills fleas, ticks & chewing lice **Top Spot®**  
for cats

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

**For Cats & Kittens**  
8 weeks or older.

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

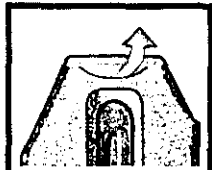


3(6)  
Applicators



(Prototype Graphics)

How to Apply **FRONTLINE<sup>®</sup>**  
**Top Spot<sup>®</sup>**  
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<sup>®</sup>**  
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 8 weeks or older.

## Top Spot® for cats

FRONTLINE provides convenient and effective flea, tick and chewing lice control for cats and kittens 8 weeks or older.

- **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)**
- **Rapidly eliminates infestations with chewing lice**
- **Can also be used on breeding, pregnant and lactating queens**
- **Waterproof**

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



Chewing Lice

XXXXXX 960

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

FRONTLINE<sup>®</sup>  
Top Spot<sup>®</sup>  
for cats



# FRONTLINE<sup>®</sup>

Top Spot<sup>®</sup>  
for cats

FRONTLINE TOP SPOT FOR CATS provides convenient and effective flea, tick and chewing lice control 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, and deer ticks** (which may carry Lyme disease) and chewing lice, apply to cats and kittens (8 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.*

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

### Frequency Of Application

When used monthly, FRONTLINE TOP SPOT FOR CATS completely controls both flea, tick and chewing lice 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.

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

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

If you have purchased this product from a veterinary clinic and are not satisfied with its performance as per the label, Merial may provide replacement product or refund of the purchase price. Please call Merial for details.



LOT NO :

For animal use only

6/12

FRONT

BACK

# FRONTLINE® Top Spot® for cats

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

### 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, tick and chewing lice 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)
- Rapidly eliminates infestations with chewing lice
- Can also be used on breeding, pregnant and lactating queens
- Waterproof

FRONTLINE® contains the active ingredient fipronil which has a unique mode of action that effectively targets fleas, ticks and chewing lice. 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, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease) and chewing lice, 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 TOP SPOT FOR CATS can also be used for the treatment and control of flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.



037 XXXXX

### FREQUENCY OF APPLICATION

When used monthly, FRONTLINE® TOP SPOT FOR CATS completely controls flea, tick and chewing lice 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 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

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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CATS compliance card x3 - Front

# FRONTLINE®

"Flea, Tick and Chewing Lice  
Protection Card"

Top Spot®  
for cats

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

Pet's Name:

Date of first  
treatment:

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Month 1



Month 2



Month 3



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

087 XXXXXX

(Prototype Graphics)

### CATS compliance card x3 - Back

Remove the adhesive backing and attach to your refrigerator door.

**Fleas, ticks and chewing lice can be a year-round problem!**

#### Spring

*Prevention*

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

#### Summer

*Prevention - Treatment*

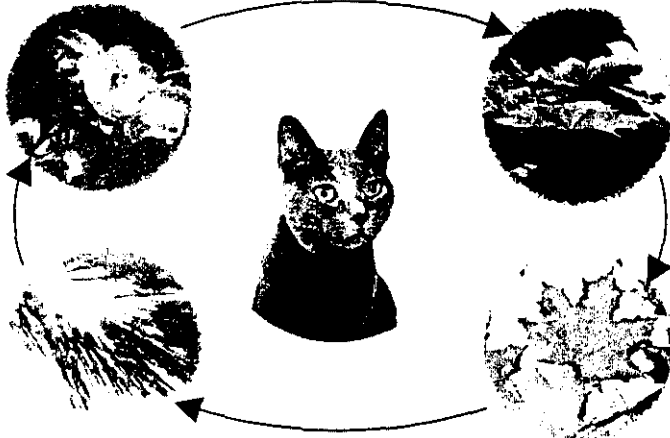
*The period of highest risk. Summer temperatures and humidity can quickly lead to huge infestations.*

#### **Flea, Tick and Chewing Lice 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 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® monthly or as needed.



#### 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).*



(Prototype Graphics)



CATS compliance card x6 - Front

# FRONTLINE®

"Flea, Tick and Chewing Lice Protection Card"

Top Spot®  
for cats







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

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Pet's Name:

Date of first treatment:



<b>Month 1</b>	<b>Month 2</b>	<b>Month 3</b>
		
<b>Month 4</b>	<b>Month 5</b>	<b>Month 6</b>
		

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

037 Y0000X

(Prototype Graphics)

### CATS compliance card x6 - Back

Remove the adhesive backing and attach to your refrigerator door.

**Fleas, ticks and chewing lice can be a year-round problem!**

#### Spring

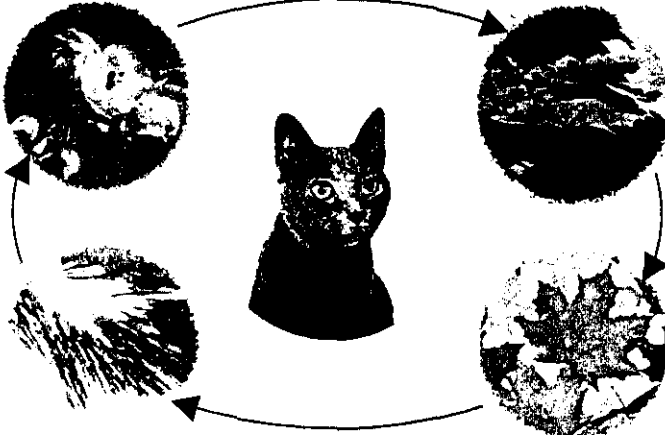
*Prevention*

*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, Tick and Chewing Lice 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 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® monthly or as needed.



(Prototype Graphics)

The diagram illustrates three identical FRONTLINE Top Spot applicators for cats, arranged horizontally. Each applicator is a teardrop-shaped container with a central vertical channel and a small tab at the top. The applicators are shown within a larger, wavy-edged frame. To the left of each applicator is the text "FRONTLINE Top Spot" and below it is the Merial logo. Below each applicator is a set of instructions for removal and dosage information.

**FRONTLINE<sup>®</sup> Top Spot<sup>®</sup>**

**MERIAL**

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

**Cat**  
**0.017 fl oz**  
**Lot #**

**FRONTLINE<sup>®</sup> Top Spot<sup>®</sup>**

**MERIAL**

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

**Cat**  
**0.017 fl oz**  
**Lot #**

**FRONTLINE<sup>®</sup> Top Spot<sup>®</sup>**

**MERIAL**

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

**Cat**  
**0.017 fl oz**  
**Lot #**

**FRONTLINE<sup>®</sup> Top Spot<sup>®</sup>**

**MERIAL**

