

AUG 11 2000

Zareen Ahmed  
 Merial  
 2100 Ronson Road  
 Iselin, NJ 08830

Dear Dr. Ahmed:

Subject:        Frontline Top Spot for Dogs  
                   EPA Reg. No. 65331-3  
                   Your submission dated May 17, 2000

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.

All references to deer ticks and lyme disease must be revised to clarify that deer ticks may carry lyme disease.

The label review manual specifies that you may not include directions for use for more product than the contents of the package. Thus, you must limit stickers to the number of pipettes in the package, either 3 or 6 pipettes, as appropriate. You must delete the directions to use the product year around, as that would require more doses than is contained in the present package. You may not include directions to use for more than 3 or 6 months at a time, as appropriate.

You must clarify the directions for using the stickers so that users who need only flea control place the stickers at three month intervals, not one month intervals.

Combine the "Satisfaction Guaranteed" statements with the Warranty Statements. Delete the statement: "The guarantee is limited to product replacement or refund of the purchase price and applies only to purchases made at a veterinary clinic." The label does not require purchase from a veterinary clinic.

**CONCURRENCES**

|         |  |  |  |  |  |  |  |  |  |
|---------|--|--|--|--|--|--|--|--|--|
| SYMBOL  |  |  |  |  |  |  |  |  |  |
| SURNAME |  |  |  |  |  |  |  |  |  |
| DATE    |  |  |  |  |  |  |  |  |  |

You must limit claims for use on puppies to puppies 10 weeks of age or older.

Revise the First Aid Statements in accordance with PR Notice 2000-3.

The Agency is reviewing the registrant's response to the requirement that a Rabbit Warning statement be included on the label of Frontline products. Depending on the outcome of this review, the Agency may require a Rabbit Warning statement, a companion animal safety study with rabbits or continued annual incident analysis.

A stamped copy of the label is enclosed for your records. 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:

AUG 11 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticides  
registered under EPA Reg. No.  
65531-3

**FRONTLINE**  
TOLENE

3(6)  
Applicators

For DOGS & PUPPIES up to 22 lbs.  
For DOGS 23-44 lbs.  
For DOGS 45-88 lbs.  
For DOGS 89-132 lbs.

For DOGS & PUPPIES  
up to 22 lbs.  
For DOGS 23-44 lbs.  
For DOGS 45-88 lbs.  
For DOGS 89-132 lbs.

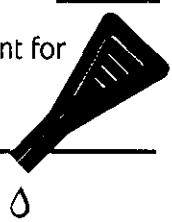
# FRONTLINE®

TOP SPOT™

3(6)  
Applicators

*Kills fleas and ticks*

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



**3(6)** Easy to Use Applicators

PHOTO  
AS PER  
WEIGHT  
OF DOG

|                   |        |
|-------------------|--------|
| ACTIVE INGREDIENT |        |
| fipronil          | 9.7%   |
| INERT INGREDIENTS | 90.3%  |
| TOTAL             | 100.0% |

KEEP OUT OF REACH OF CHILDREN  
**CAUTION**

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



LIFT HERE TO OPEN

038 002224 - A 9909

# FRONTLINE<sup>®</sup>

**TOP SPOT<sup>™</sup>**

For DOGS & PUPPIES  
up to 22 lbs.

For DOGS 23-44 lbs.

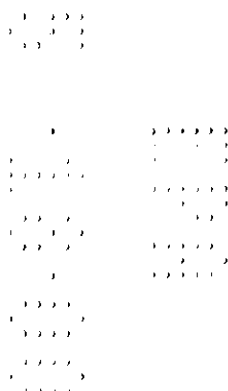
For DOGS 45-88 lbs.

For DOGS 89-132 lbs.

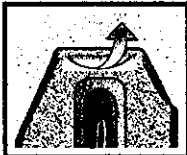
FRONTLINE provides convenient and effective flea and tick control for (dogs and puppies up to 22 lbs., dogs weighing 23-44 lbs., dogs weighing 45-88 lbs., dogs weighing 89-132 lbs.)

- *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 (the major carrier of 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.



# How to Apply **FRONTLINE** TOP SPOT



**1. To remove applicator from child-resistant package:** Use scissors. Or lift and remove plastic tab to expose foil, then peel down.



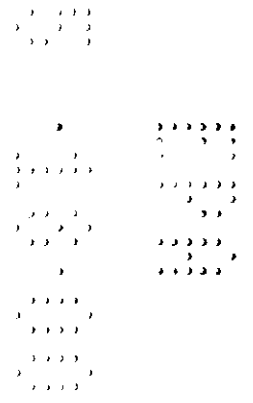
**2. To open applicator:** Hold upright and snap applicator tip away from face and body.

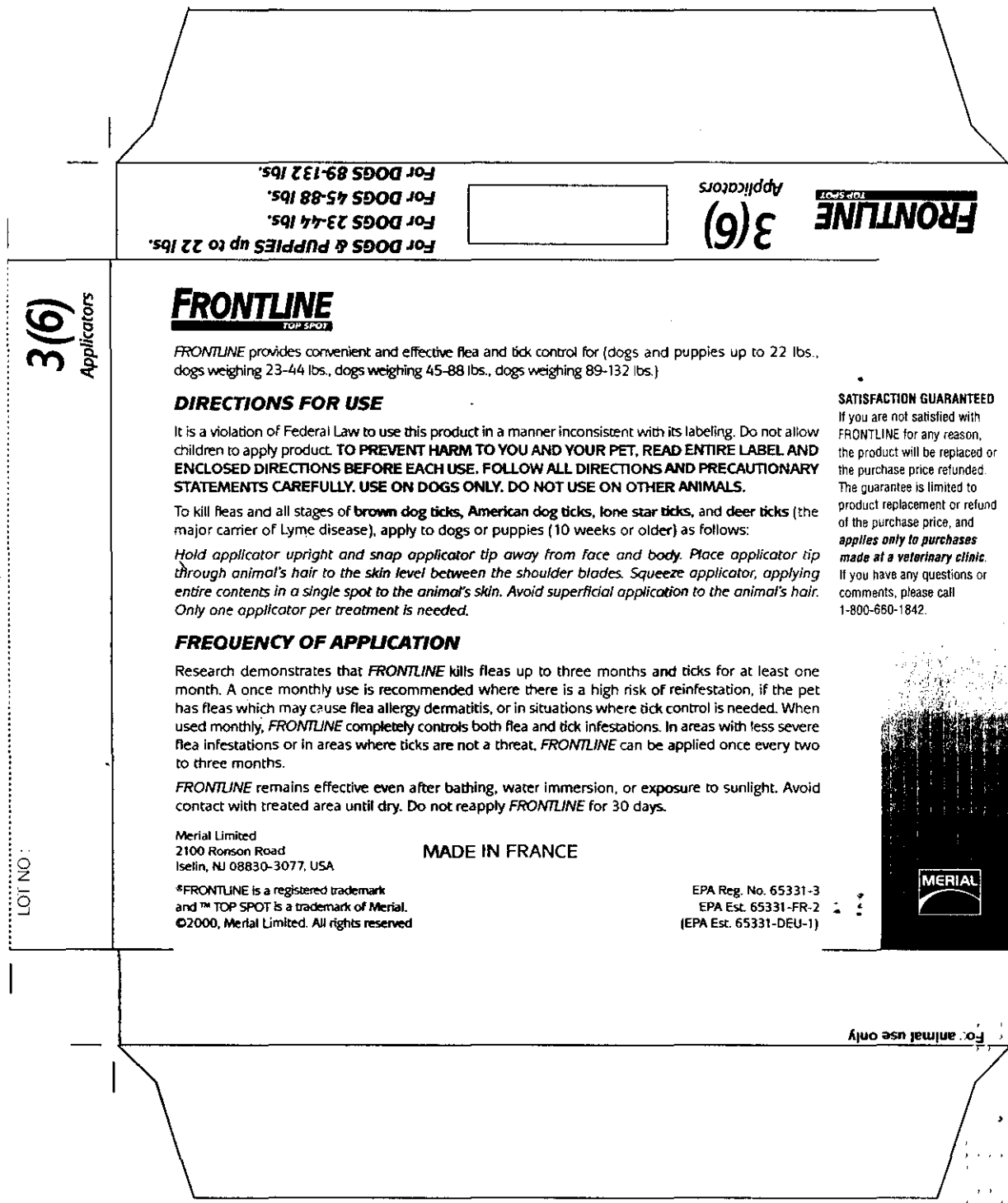


**3. To apply FRONTLINE:** Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin.

INSERT COVER TAB HERE

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





For DOGS & PUPPIES up to 22 lbs.  
For DOGS 23-44 lbs.  
For DOGS 45-88 lbs.  
For DOGS 89-132 lbs.



3(6) Applicators

FRONTLINE TOP SPOT

3(6) Applicators

### FRONTLINE TOP SPOT

FRONTLINE provides convenient and effective flea and tick control for (dogs and puppies up to 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 OTHER ANIMALS.**

To kill fleas and all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (the major carrier of Lyme disease), apply to dogs or puppies (10 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

Research demonstrates that FRONTLINE kills fleas up to three months and ticks for at least one month. A once monthly use is recommended where there is a high risk of reinfestation, if the pet has fleas which may cause flea allergy dermatitis, or in situations where tick control is needed. When used monthly, FRONTLINE completely controls both flea and tick infestations. In areas with less severe flea infestations or in areas where ticks are not a threat, FRONTLINE can be applied once every two to three months.

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.

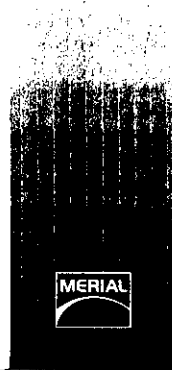
Merial Limited  
2100 Ronson Road  
Iselin, NJ 08830-3077, USA

MADE IN FRANCE

®FRONTLINE is a registered trademark and ™ TOP SPOT is a trademark of Merial. ©2000, Merial Limited. All rights reserved

EPA Reg. No. 65331-3  
EPA Est. 65331-FR-2  
(EPA Est. 65331-DEU-1)

**SATISFACTION GUARANTEED**  
If you are not satisfied with FRONTLINE for any reason, the product will be replaced or the purchase price refunded. The guarantee is limited to product replacement or refund of the purchase price, and **applies only to purchases made at a veterinary clinic.** If you have any questions or comments, please call 1-800-660-1842.



LOT NO :

For animal use only

# FRONTLINE<sup>®</sup>

## TOP SPOT<sup>™</sup>

### FOR DOGS AND PUPPIES

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 dogs and puppies.

- 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 (the major carrier of 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 DOGS ONLY. 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 (the major carrier of Lyme disease), apply to dogs or puppies (10 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

Research demonstrates that FRONTLINE kills fleas up to three months and ticks for at least one month. A once monthly use is recommended where there is a high risk of reinfestation, if the pet has fleas which may cause flea allergy dermatitis, or in situations where tick control is needed. When used monthly, FRONTLINE completely controls both flea and tick infestations.



\* 7 2 5 5 8 A \*

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In areas with less severe flea infestations, or in areas where ticks are not a threat, FRONTLINE can be applied once every two to three months.

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

**IF SWALLOWED:** Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. IF person is unconscious, do not give anything by mouth and do not induce vomiting.

**IF IN EYES:** Flush eyes with plenty of water. Call a physician 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 puppies under 10 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.

#### HOW SUPPLIED

For easy and convenient treatment, FRONTLINE is available in sizes for small dogs and puppies up to 22 lbs., medium dogs 23-44 lbs., large dogs 45-88 lbs., and extra large dogs 89-132 lbs.

#### 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. 65331-3

#### Merial Limited

2100 Ronson Road  
Iselin, NJ 08830-3077, USA

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and TOP SPOT is a trademark of Merial.  
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Notice TOP SPOT USA Chiens NEW-LOOK - EDIT-PUB - 24/03/2000 - S. CLION - Noir

**For  
DOGS**

# FRONTLINE®

**"Flea and tick protection card"**

*Apply FRONTLINE® monthly for continuous protection against fleas and ticks*

Pet's Name :

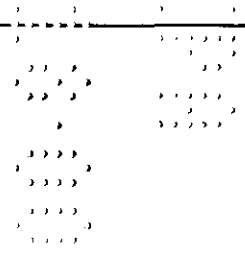
Date of first  
treatment :



*Place calendar stickers on same date each month as a reminder to apply FRONTLINE®*

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Carte Rappel SPOT ON USA - EDIT-PUB - 15/03/2000 - S. CLION - Quadriè





Remove the adhesive backing and attach to your refrigerator door

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

**Spring**

Prevention

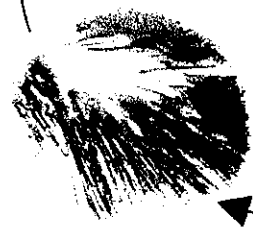
*Fleas and ticks start to breed more quickly as spring progresses.*



**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

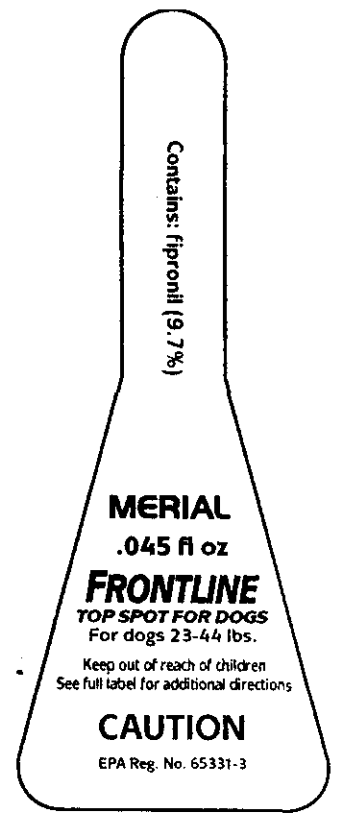
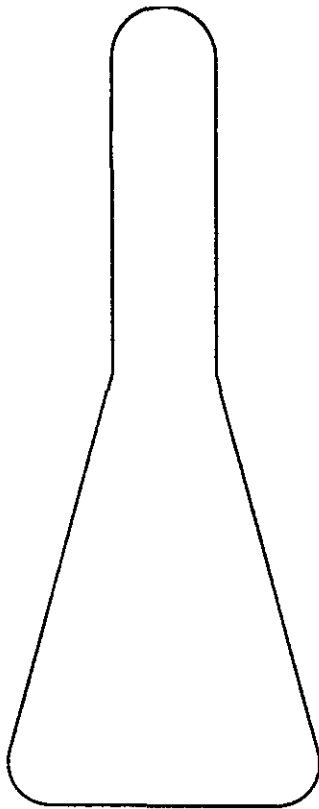
*Prevents reinfestation from newly emerged adult fleas and all stages of brown dog ticks, American dog ticks, lone star ticks and deer ticks (the major carrier of Lyme disease).*

**Flea and Tick Protection Card**  
**Instructions for Use**

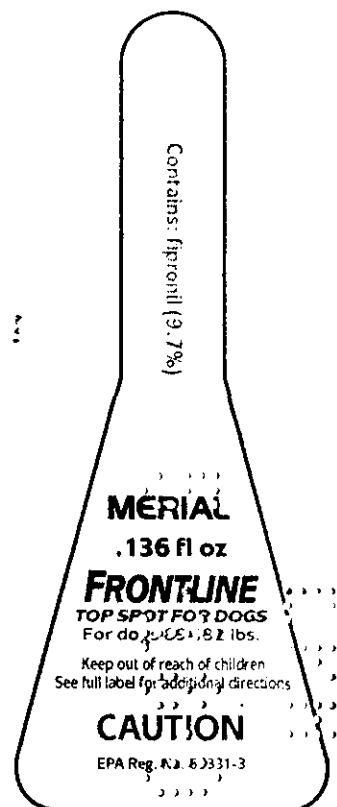
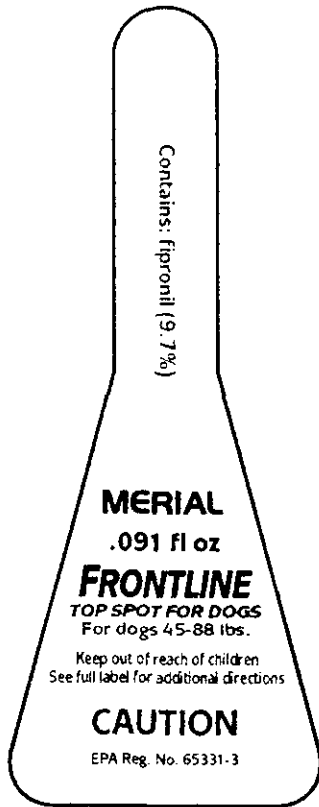
Monthly treatment with **FRONTLINE** is the best way to ensure your pet remains flea - and tick - free all year round. The calendar stickers on the front of this card will help you remember to apply **FRONTLINE** monthly.

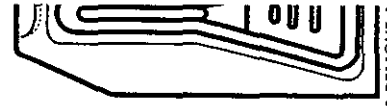
- 1 - Write the date of your pet's first treatment in the box shown.
- 2 - After treating your pet, peel off the sticker corresponding to the current month.
- 3 - Place the sticker on your calendar on the same day the next month as a reminder to apply **FRONTLINE**.





Shown 125% of actual size

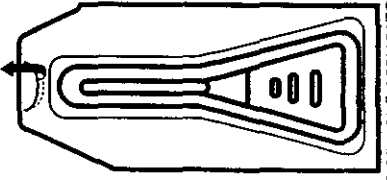




**FRONTLINE**  
(fipronil)



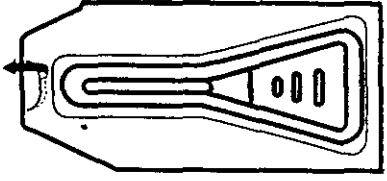
TO REMOVE APPLICATOR:  
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.



**FRONTLINE**  
(fipronil)



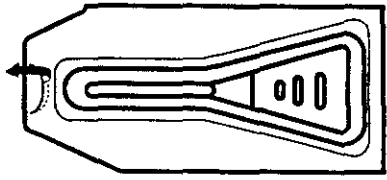
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**FRONTLINE**  
(fipronil)



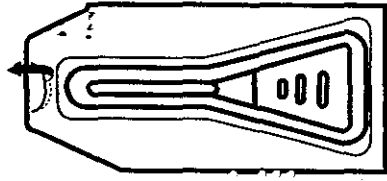
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**FRONTLINE**  
(fipronil)



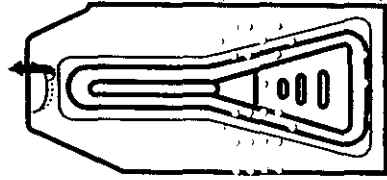
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**FRONTLINE**  
(fipronil)



TO REMOVE APPLICATOR:  
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**FRONTLINE**  
(fipronil)



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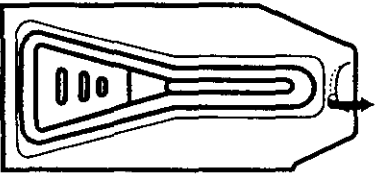
035 000672 - B0003



**FRONTLINE**  
(fipronil)



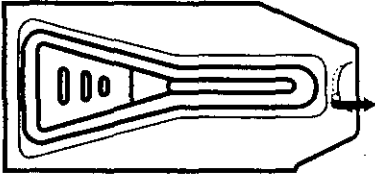
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**FRONTLINE**  
(fipronil)



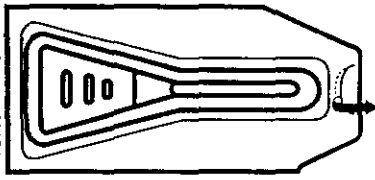
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**FRONTLINE**  
(fipronil)



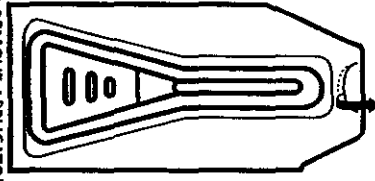
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**FRONTLINE**  
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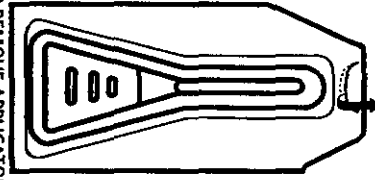
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**FRONTLINE**  
(fipronil)



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