

65331-3

7/28/2011

10 of 10



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

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION PREVENTION

July 28, 2011

Karen C. Cunningham  
Head, Regulatory Affairs  
Merial Limited  
3239 Satellite Blvd. Building 500, Office 113  
Duluth, GA 30096-4640

Subject: Application for Pesticide Amendment  
Frontline Top Spot for Dogs  
EPA Reg. No. 65331-3  
Your Submission Dated May 24, 2011  
Decision No: 449976

Dear Ms. Cunningham:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at:  
[Benmhend.driss@epa.gov](mailto:Benmhend.driss@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

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

Enclosure: *Label stamped "Accepted"*

20f10



# How to Apply FRONTLINE® Top Spot® FOR DOGS



**Step 1.**  
**OPEN Applicator**  
Hold upright with foil side toward you and snap applicator tip.

**Step 2.**  
**APPLY FRONTLINE TOP SPOT**  
Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the dog's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

**Questions or Comments?**  
Call: 1-800-660-1842,  
Monday-Friday, 8am-8pm EST or  
visit us at [www.FRONTLINE.com](http://www.FRONTLINE.com)

Technical area  
No print here  
except prod. barcode



# FRONTLINE® Top Spot® FOR DOGS

Kills fleas, ticks, chewing lice & mosquitoes

- Fast-acting
- Long-lasting
- Waterproof

EPA Reg. No. 65331-3  
EPA Est. 65331-FR-2  
MADE IN FRANCE

Kills ticks, including those that may transmit Lyme disease

**ACTIVE INGREDIENTS:**  
Fipronil.....9.7%  
**INERT INGREDIENTS:**.....90.3%  
**TOTAL:**.....100%  
Contains 1-0.091 fl oz (2.68 ml) applicator,  
1 monthly dose

1  
2  
For use ONLY on DOGS  
**45 to 88 lbs**



See inside panels for FIRST AID and PRECAUTIONARY statements.  
KEEP OUT OF REACH OF CHILDREN  
**CAUTION**

BACK

FRONT

## FRONTLINE® Top Spot® FOR DOGS

For use ONLY on DOGS & PUPPIES 8 weeks or older:  
Fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice, sarcoptic mites and mosquitoes.

**ACTIVE INGREDIENT**  
fipronil.....9.7%  
**INERT INGREDIENTS**.....90.3%  
**TOTAL**.....100.0%  
**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

FRONTLINE® TOP SPOT® for Dogs:

- Fleas**
    - Kills fleas
    - Kills newly emerged adult fleas before they lay eggs
    - Stops existing infestations and prevents establishment of new infestations
    - Kills fleas which may cause flea allergy dermatitis
  - Ticks**
    - Kills all life stages of ticks (larva, nymph and adult), including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)
    - Kills ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases
  - Lice**
    - Rapidly eliminates chewing lice infestations
  - Mites**
    - Aids in control of sarcoptic mange infestations
  - Mosquitoes**
    - Kills mosquitoes
- FRONTLINE TOP SPOT is approved for use on all dogs, including:
- Breeding, pregnant, and lactating bitches
  - Puppies as young as 8 weeks

One spot application is all that's needed:  
FRONTLINE TOP SPOT spreads from the single point of application, rapidly covering the entire dog and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing FRONTLINE TOP SPOT onto the skin and hair coat, so it keeps working even if the dog gets wet.  
Fleas, ticks and chewing lice are killed quickly after coming into contact with a treated dog. Fleas and ticks do not need to bite the dog in order to die.

**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 RABBITS. DO NOT USE ON OTHER ANIMALS. To kill fleas, ticks, chewing lice and mosquitoes apply FRONTLINE TOP SPOT for Dogs as follows:

- **OPEN Applicator**  
Hold upright with foil side toward you and snap applicator tip.
  - **APPLY FRONTLINE TOP SPOT**  
Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the animal's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.
- FRONTLINE TOP SPOT for Dogs is approved for use on breeding, pregnant, and lactating bitches and puppies as young as 8 weeks.  
FRONTLINE TOP SPOT remains effective even after bathing, water immersion, or exposure to sunlight.

**FREQUENCY OF APPLICATION**  
When used monthly, FRONTLINE TOP SPOT completely controls flea, tick and chewing lice infestations. Do not reapply FRONTLINE TOP SPOT for 30 days.  
FRONTLINE TOP SPOT kills adult fleas for up to three months, however, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly

application may be needed.  
FRONTLINE TOP SPOT kills ticks for at least one month. A once monthly application is recommended where tick control is needed.  
FRONTLINE TOP SPOT kills all life stages of ticks (larva, nymph and adult). FRONTLINE TOP SPOT kills ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.  
FRONTLINE TOP SPOT kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.  
FRONTLINE TOP SPOT aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.  
FRONTLINE TOP SPOT kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days with a monthly application.

**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: Nonrefillable container. Do not reuse or refill 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:** 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 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.

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS. CAUTION.**  
Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

**HAZARDS TO DOMESTIC ANIMALS.**  
For external use only. Do not use on puppies 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. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-660-1842, Monday-Friday, 8am-8pm EST.

**PHYSICAL OR CHEMICAL HAZARDS**  
**COMBUSTIBLE:** Do not use or store near heat or open flame.

**HOW SUPPLIED**  
For easy and convenient treatment, FRONTLINE TOP SPOT for Dogs is available in sizes for use ONLY on small dogs and puppies 8 weeks or older and up to 22 lbs., medium dogs 23-44 lbs., large dogs 45-88 lbs., and extra large dogs 89-132 lbs.

**WARRANTY**  
To the extent consistent with applicable law, 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.

**Merial Limited**  
3239 Satellite Blvd.  
Duluth, GA 30076-4543, USA  
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ACCEPTED  
JUL 28 2011

INSIDE PANELS

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

1 Contains 1-0.023 fl oz (0.67 ml) applicator  
2 Contains 1-0.045 fl oz (1.34 ml) applicator  
3 Contains 1-0.136 fl oz (4.02 ml) applicator

2 For use ONLY on DOGS & PUPPIES 8 Weeks or Older and up to

22 lbs

For use ONLY on DOGS

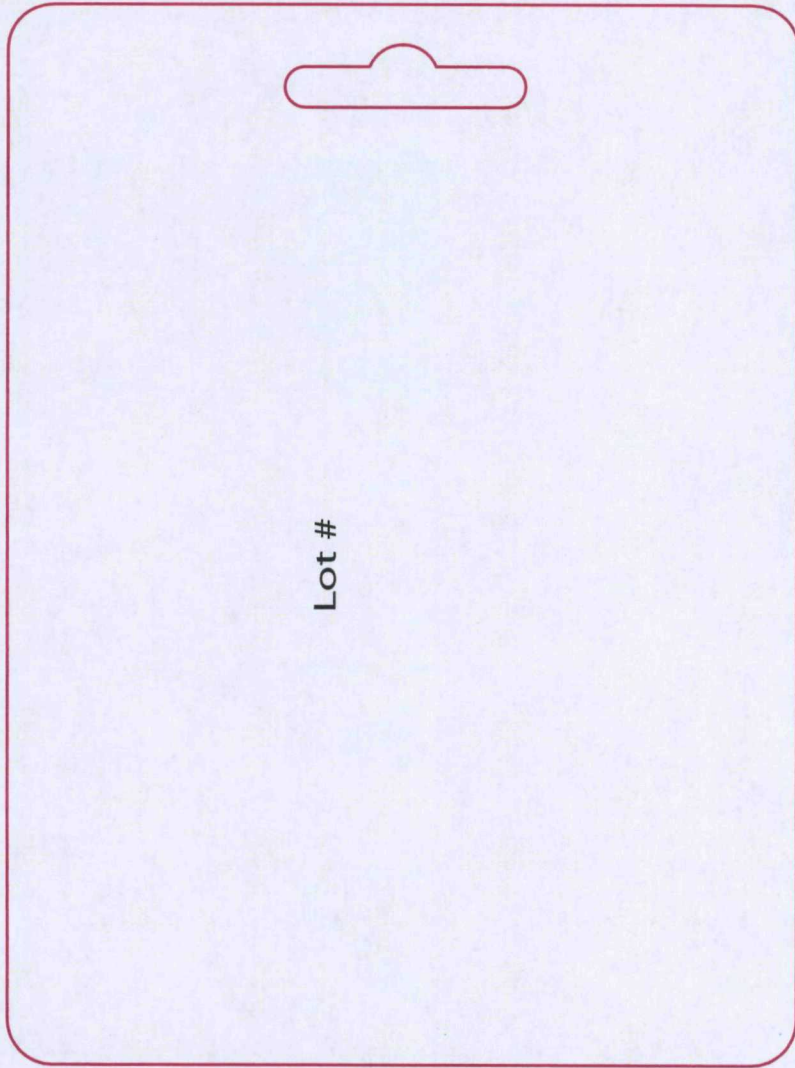
23 to 44 lbs

For use ONLY on DOGS

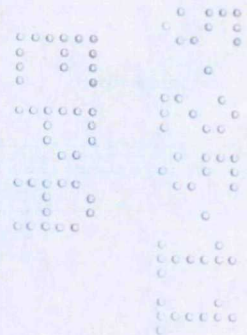
89 to 132 lbs

EPA. Reg. No: 65331-3

A 10222009 10h25 SK 2011  
B 11042009 10h25 SK 2011  
C 11112009 10h25 SK 2011  
E 13 SEPT 2010 TR  
F 16 SEPT 2010 TR  
G 10 MAY 2011 TR  
H 20 MAY 2011 TR



Lot #



**FRONTLINE®**  
Top Spot®  
FOR DOGS

For use ONLY on DOGS & PUPPIES 8 Weeks or Older and up to **22 lbs**  
For use ONLY on DOGS **45 to 88 lbs**

For use ONLY on DOGS **23 to 44 lbs**  
For use ONLY on DOGS **89 to 132 lbs**

**3(6)**  
doses

# FRONTLINE®

## Top Spot® FOR DOGS

**Kills fleas, ticks, chewing lice & mosquitoes**

- Fast-acting
- Long-lasting
- Waterproof

**Kills ticks, including those that may transmit Lyme disease**

For use ONLY on DOGS & PUPPIES 8 Weeks or Older and up to **22 lbs**  
For use ONLY on DOGS **23 to 44 lbs**  
For use ONLY on DOGS **45 to 88 lbs**  
For use ONLY on DOGS **89 to 132 lbs**

**ACTIVE INGREDIENT:**  
Fipronil: ..... 9.7%  
**INERT INGREDIENTS:** ... 90.3%  
**TOTAL:** ..... 100%

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

SEE INSERT FOR FIRST AID AND PRECAUTIONARY STATEMENTS  
**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

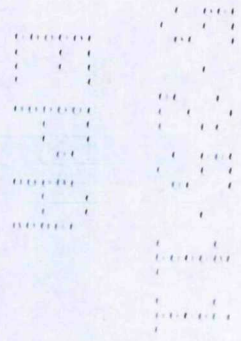
**MERIAL**

**3(6)**  
doses

Lift Here



PROTOTYPE GRAPHICS



# FRONTLINE® Top Spot® FOR DOGS

### FRONTLINE® TOP SPOT® for Dogs is:

- Fast-acting
- Long-lasting
- Waterproof

### One spot application is all that's needed:

FRONTLINE TOP SPOT spreads from the single point of application, rapidly covering the entire dog and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing FRONTLINE TOP SPOT onto the skin and hair coat, so it keeps working even if the dog gets wet.

Fleas, ticks and chewing lice are killed quickly after coming into contact with a treated dog. Fleas and ticks do not need to bite the dog in order to die.

### FRONTLINE TOP SPOT for Dogs:

#### Fleas

- Kills fleas
- Kills newly emerged adult fleas before they lay eggs
- Stops existing infestations and prevents establishment of new infestations
- Kills fleas which may cause flea allergy dermatitis

#### Ticks

- Kills all life stages of ticks (larva, nymph and adult), including deer ticks (*Ixodes scapularis*), brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*) and lone star ticks (*Amblyomma americanum*)
- Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases

#### Lice

- Rapidly eliminates chewing lice infestations

#### Mites

- Aids in control of sarcoptic mange infestations

FRONTLINE TOP SPOT is approved for use on all dogs, including:

- Breeding, pregnant, and lactating bitches
- Puppies as young as 8 weeks

#### Mosquitoes

- Kills mosquitoes



Adult Fleas



Ticks

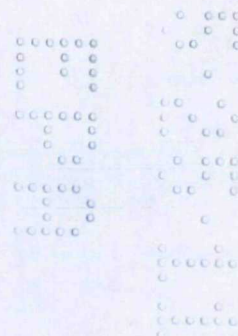


Chewing Lice



Mosquitoes

PROTOTYPE GRAPHICS





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

For use ONLY on DOGS  
DOGS & PUPPIES  
8 WEEKS OF AGE  
AND UP TO  
22 lbs.  
For use ONLY on DOGS  
23 to 44 lbs.  
3 (6) doses

# FRONTLINE<sup>®</sup>

## Top Spot<sup>®</sup> FOR DOGS

FRONTLINE TOP SPOT for Dogs provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice, sarcoptic mites and mosquitoes for use ONLY on (dogs and puppies 8 weeks or older and 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 RABBITS. DO NOT USE ON OTHER ANIMALS.**

- To kill fleas, ticks, chewing lice and mosquitoes apply FRONTLINE TOP SPOT for Dogs as follows:
- To REMOVE Applicator: Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.
  - OPEN Applicator. Hold upright with foil side toward you and snap applicator tip.
  - APPLY FRONTLINE TOP SPOT. Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the animal's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

FRONTLINE TOP SPOT for Dogs is approved for use on breeding, pregnant, and lactating bitches and puppies as young as 8 weeks.  
FRONTLINE TOP SPOT remains effective even after bathing, water immersion, or exposure to sunlight.

### Frequency of Application

When used monthly, FRONTLINE TOP SPOT completely controls flea, tick and chewing lice infestations. Do not reapply FRONTLINE TOP SPOT for 30 days.  
FRONTLINE TOP SPOT kills adult fleas for up to three months, however, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.  
FRONTLINE TOP SPOT kills ticks for at least one month. A once monthly application is recommended where tick control is needed. FRONTLINE TOP SPOT kills all life stages of ticks (larva, nymph and adult). FRONTLINE TOP SPOT kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.  
FRONTLINE TOP SPOT kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.  
FRONTLINE TOP SPOT aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.  
FRONTLINE TOP SPOT kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days, with a monthly application.



Please call our experts at  
**1-800-660-1842**,  
Monday-Friday,  
8am-8pm EST with any  
questions or comments  
about flea, tick, chewing lice,  
sarcoptic mite or mosquito  
control or FRONTLINE TOP SPOT.



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

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LOT NO:  
x00000xx

EPA Reg. No. 00000-0  
(EPA Est. 00000-XX-0)  
(EPA Est. 00000-XX-0)

For dog use only

PROTOTYPE GRAPHICS

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

**TO REMOVE APPLICATOR:**  
Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.

0.023 fl oz Lot #

**DOG 22**

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

**TO REMOVE APPLICATOR:**  
Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.

0.045 fl oz Lot #

**DOG 44**

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

**TO REMOVE APPLICATOR:**  
Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.

0.091 fl oz Lot #

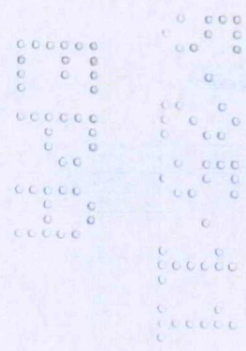
**DOG 88**

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

**TO REMOVE APPLICATOR:**  
Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.

0.136 fl oz Lot #

**DOG 132**



**MERIAL**  
Contains: fipronil (9.7%)

**ONLY FOR DOGS & PUPPIES**  
9 weeks of age and up to 22 lbs.



0.023 fl oz  
**FRONTLINE® Top Spot®**

Keep out of reach of children  
See full label for additional directions  
**CAUTION**  
EPA Reg. No. 65331-3

**MERIAL**  
Contains: fipronil (9.7%)

**ONLY FOR DOGS**  
23-44 lbs.



0.045 fl oz  
**FRONTLINE® Top Spot®**

Keep out of reach of children  
See full label for additional directions  
**CAUTION**  
EPA Reg. No. 65331-3

**MERIAL**  
Contains: fipronil (9.7%)

**ONLY FOR DOGS**  
45-88 lbs.




0.091 fl oz  
**FRONTLINE® Top Spot®**

Keep out of reach of children  
See full label for additional directions  
**CAUTION**  
EPA Reg. No. 65331-3

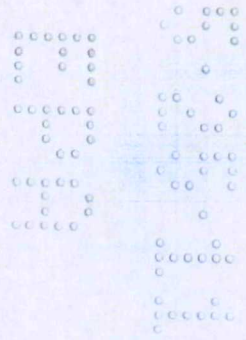
**MERIAL**  
Contains: fipronil (9.7%)

**ONLY FOR DOGS**  
89-132 lbs.



0.136 fl oz  
**FRONTLINE® Top Spot®**

Keep out of reach of children  
See full label for additional directions  
**CAUTION**  
EPA Reg. No. 65331-3







# FRONTLINE®

See other side for more...

**Some tips and other information**

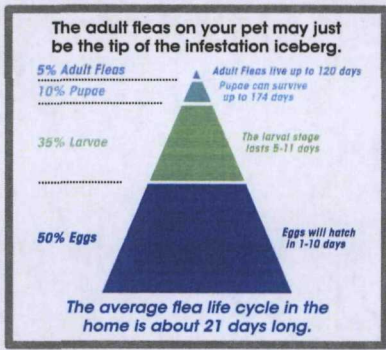


- ✓ To successfully control fleas and ticks, all dogs and cats must be treated with their own dose of FRONTLINE®.
- ✓ Apply according to label instructions, ensuring the product is applied to the skin, not on top of the fur and not near the collar. It may be helpful to remove the collar before application, so it doesn't absorb the product.
- ✓ Remember, your pet needs to be dry at the time FRONTLINE is applied and remain dry 24 hours after application.
- ✓ Verify pipette is empty after application (multiple squeezes may be necessary to apply the entire dose).
- ✓ Even indoor pets need flea and tick control because you or other pets in the household may bring fleas into the home. These fleas can lead to a flea infestation.

**FLEAS: What you need to know**



It can take up to **3 months** to get rid of a serious flea infestation because of all of the flea life stages that existed **BEFORE** you started using FRONTLINE.



Front

**Calendar Reminder stickers**

To ensure continued protection of your pets, use these stickers as a reminder to apply and re-purchase FRONTLINE.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

**Don't forget to re-purchase!**

Place the remaining stickers on your calendar as a reminder to apply FRONTLINE monthly.

**QUESTIONS?**  
Contact your veterinarian or call our technical experts at **1-800-660-1842**, Monday-Friday, 8am-8pm. For more information, visit [www.FRONTLINE.com](http://www.FRONTLINE.com)



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**6 Months**  
use all 6 stickers



**3 Months**



Back with stickers

037 000000

