

65331-5

10-24-2003

1/13



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

OCT 24 2003

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Timothy A. Dotson  
Merial  
3239 Satellite Blvd.  
Duluth, GA 30096

Dear Mr. Dotson:

Subject: Frontline Top Spot for Dogs  
EPA Reg. No. 65331-35  
Submission dated 7/23/03

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.

Delete the reference to mosquito "infestations" on dogs. Mosquitoes do not infest dogs as do fleas, ticks, and chewing lice.

One copy of the finished labeling must be submitted prior to releasing the product for shipment. If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,

A handwritten signature in cursive script that reads "Ann Sibold".

Linda Arrington  
Acting Product Manager 10  
Insecticide Branch  
Registration Division (7505C)



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

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OCT 29 2003

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Timothy A. Dotson  
Merial  
3239 Satellite Blvd.  
Duluth, GA 30096

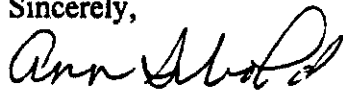
Dear Mr. Dotson:

Subject: Revised acceptance letter  
Frontline Plus for Dogs  
EPA Reg. No. 65331-5  
Submission dated 7/23/03

The subject line of the letter dated Oct 24, 2003 should be corrected to read as follows:  
Frontline Plus for Dogs  
EPA Reg. No. 65331-5

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

Sincerely,

*for*   
Linda Arrington  
Acting Product Manager 10  
Insecticide Branch  
Registration Division (7505C)

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
OCT 24 2003

Under the Fungicide, Insecticide, and Rodenticide Act,  
as amended, and the pesticide  
registered under EPA Reg. No.  
65331-5

FRONTLINE®  
*Plus*  
for dogs  
For Dogs & Puppies 8 weeks or  
older and up to 22 lbs.  
For Dogs 23-44 lbs.  
For Dogs 45-88 lbs.  
For Dogs 89-132 lbs.  
3(6)  
Applicators

# FRONTLINE®

3(6)  
Applicators

Kills fleas, flea eggs, ticks, chewing lice  
& mosquitoes

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

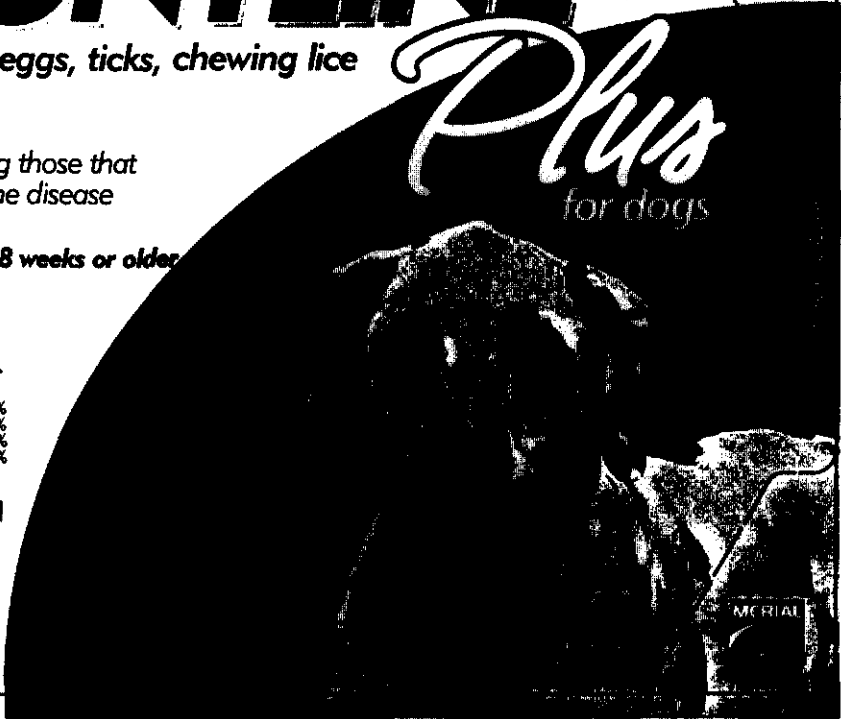
*Plus*  
for dogs

For Dogs & Puppies 8 weeks or older  
and up to 22 lbs.  
For Dogs 23-44 lbs.  
For Dogs 45-88 lbs.  
For Dogs 89-132 lbs.

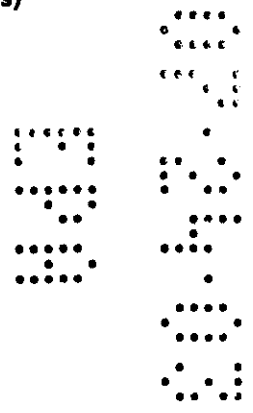
ACTIVE INGREDIENTS	
fluralaner.....	9.8%
(S)-methoprene.....	8.8%
INERT INGREDIENTS.....	81.4%
TOTAL.....	100.0%

**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



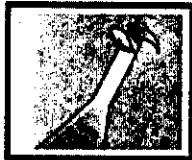
(Prototype Graphics)



# How to Apply **FRONTLINE<sup>®</sup>** *Plus* for dogs



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



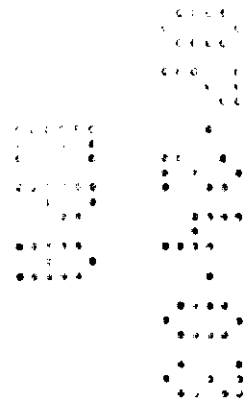
**2. Open Applicator**  
Hold upright and snap applicator tip away from face and body.



**3. Apply FRONTLINE<sup>®</sup> PLUS FOR DOGS**  
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<sup>®</sup> Plus for dogs

FRONTLINE PLUS FOR DOGS provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes for (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.)

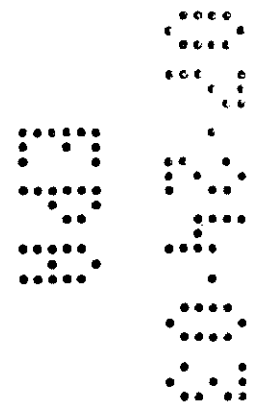
- **Stops and prevents infestations**
- **Kills adult fleas, flea eggs & flea larvae**
- **Prevents all flea stages (eggs, larvae, pupae) from developing**
- **Kills fleas which may cause flea allergy dermatitis**
- **Kills all stages of deer ticks (which may carry Lyme disease), brown dog ticks, American dog ticks & lone star ticks**
- **Kills mosquitoes**
- **Prevents and controls reinfestations**
- **Rapidly eliminates infestations with chewing lice**
- **Aids in control of sarcoptic mange infestations**
- **Can also be used on breeding, pregnant and lactating bitches**
- **Fast-acting**
- **Long-lasting**
- **Waterproof**
- **Convenient to use**

FRONTLINE PLUS FOR DOGS 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, ticks and chewing lice.



- Flea Adult
- Flea Eggs
- Flea Larvae
- Flea Pupae
- Brown Dog Tick
- Lone Star Tick
- Deer Tick
- American Dog Tick
- Chewing Lice
- Mosquito

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6/13

3(6)

For Dogs & Puppies 8 weeks or older and up to 22 lbs.  
For Dogs 23-44 lbs.  
For Dogs 45-88 lbs.  
For Dogs 89-132 lbs.

*Plus*  
**FRONTLINE**

3(6)

# FRONTLINE<sup>®</sup> *Plus* for dogs

**FRONTLINE PLUS FOR DOGS** provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes for (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, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease), chewing lice and mosquitoes, apply to dogs or puppies (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 PLUS** aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

**FRONTLINE PLUS FOR DOGS** can also be used for the treatment and control of flea, tick, chewing lice and mosquitoes infestations on breeding, pregnant and lactating bitches.

### Frequency Of Application

When used monthly, **FRONTLINE PLUS FOR DOGS** completely breaks the flea life cycle and controls tick and chewing lice infestations.

Research demonstrates that **FRONTLINE PLUS** kills adult fleas, flea eggs, and flea larvae for up to three months. **FRONTLINE PLUS** also prevents development of all flea stages for up to three months. Although **FRONTLINE PLUS** can control fleas for up to three months, 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** kills ticks for at least one month. A once monthly application is recommended where tick control is needed.

**FRONTLINE PLUS** kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

With a monthly application, **FRONTLINE PLUS** kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

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

MADE IN FRANCE

EPA Reg. No. 65331-5  
EPA Est. 65331-FR-2  
(EPA Est. 65331-DEU-1)  
(EPA Est. 65331-GA-1)  
(EPA Est. XXXXX-XXX-X)

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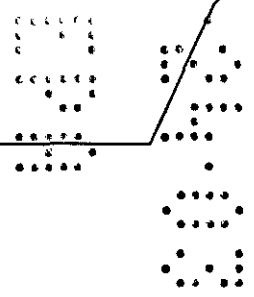
Please call our experts at 1-800-660-1842 if you have any questions or comments about flea, tick, lice and mosquito control or FRONTLINE PLUS.

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



# FRONTLINE® Plus for dogs

**FOR DOGS & PUPPIES 8 weeks or older**  
Convenient spot treatment for fast-acting,  
long-lasting control of fleas, ticks and chewing lice.  
**FRONTLINE® PLUS also kills mosquitoes.**

#### ACTIVE INGREDIENTS

fipronil: .....	9.8%
(S)-methoprene .....	8.8%
<b>INERT INGREDIENTS .....</b>	<b>81.4%</b>
<b>TOTAL .....</b>	<b>100.0%</b>

#### KEEP OUT OF REACH OF CHILDREN CAUTION

**FRONTLINE® PLUS FOR DOGS** provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes for dogs and puppies.

- Stops and prevents infestations
- Kills adult fleas, flea eggs, and 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, and lone star ticks
- Kills mosquitoes
- Prevents and controls reinfestations
- Rapidly eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Can also be used on breeding, pregnant and lactating bitches
- Fast-acting
- Long-lasting
- Waterproof
- Convenient to use

**FRONTLINE® PLUS FOR DOGS** 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, ticks and chewing lice.

#### 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, all stages of brown dog ticks, American dog ticks, lone star ticks, deer ticks (which may carry Lyme disease), chewing lice and mosquitoes, apply to dogs or puppies (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® PLUS** aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

**FRONTLINE® PLUS FOR DOGS** can also be used for the treatment and control of flea, tick, chewing lice and mosquito infestations on breeding, pregnant and lactating bitches.



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#### FREQUENCY OF APPLICATION

When used monthly, **FRONTLINE® PLUS FOR DOGS** completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that **FRONTLINE® PLUS** kills adult fleas, flea eggs, and flea larvae for up to three months. **FRONTLINE® PLUS** also prevents development of all flea stages for up to three months. Although **FRONTLINE® PLUS** can control fleas for up to three months, 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** kills ticks for at least one month. A once monthly application is recommended where tick control is needed. **FRONTLINE® PLUS** kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed. With a monthly application, **FRONTLINE® PLUS** kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days. **FRONTLINE® PLUS FOR DOGS** 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.** 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: Do not reuse 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:** 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 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 for 24-hour assistance.

##### PHYSICAL OR CHEMICAL HAZARDS

**COMBUSTIBLE:** Do not use or store near heat or open flame.

#### HOW SUPPLIED

For easy and convenient treatment, **FRONTLINE® PLUS FOR DOGS** is available in sizes for 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

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. 65331-5

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



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8/13

DOGS compliance card x3 - Front

# FRONTLINE®

"Flea, Tick, Chewing Lice and Mosquito Protection Card"

## Plus for dogs

Apply FRONTLINE PLUS FOR DOGS 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

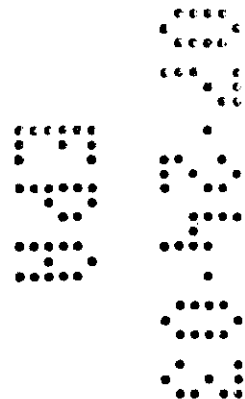
Month 3



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

087 20000X

(Prototype Graphics)





### DOGS compliance card x3 - Back

Remove the adhesive backing and attach to your refrigerator door

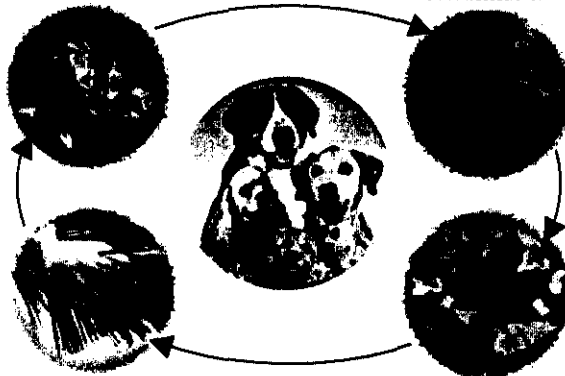
*Fleas, Ticks, Chewing Lice and Mosquitoes can be a year-round problem!*

#### 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, Tick, Chewing Lice and Mosquito Protection Card

##### Instructions for Use

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

- 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® PLUS FOR DOGS monthly or as needed.



(Prototype Graphics)



10/13

DOGS compliance card x6 - Front

# FRONTLINE®

"Flea, Tick, Chewing Lice and Mosquito Protection Card"

## Plus for dogs

Apply FRONTLINE PLUS FOR DOGS monthly, as directed, for continuous protection against fleas, ticks and chewing lice.

Pet's Name: \_\_\_\_\_

Date of first treatment: \_\_\_\_\_

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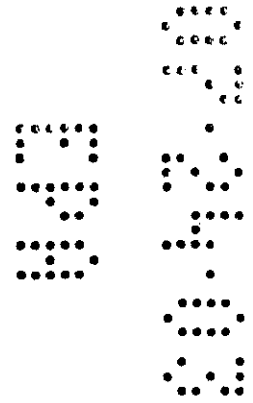


Month 1	Month 2	Month 3
Month 4	Month 5	Month 6

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

497 XXXXXX

(Prototype Graphics)



11/13

### DOGS compliance card x6 - Back

Remove the adhesive backing and attach to your refrigerator door

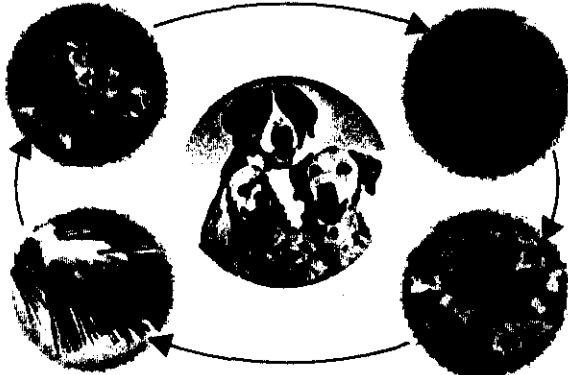
*Fleas, Ticks, Chewing Lice and Mosquitoes can be a year round problem!*

#### 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, Tick, Chewing Lice and Mosquitoes Protection Card

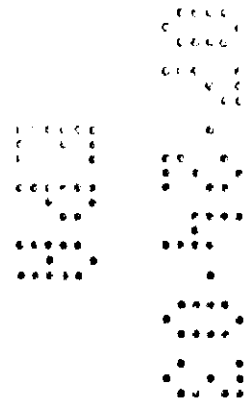
##### Instructions for Use

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

- 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 PLUS FOR DOGS monthly or as needed.



(Prototype Graphics)



**FRONTLINE<sup>Plus</sup>**

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

Dog 22  
0.023 fl oz  
Lot #

**FRONTLINE<sup>Plus</sup>**

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

Dog 22  
0.023 fl oz  
Lot #

**FRONTLINE<sup>Plus</sup>**

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

Dog 22  
0.023 fl oz  
Lot #

**FRONTLINE<sup>Plus</sup>**

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

Dog 44  
0.045 fl oz  
Lot #

**FRONTLINE<sup>Plus</sup>**

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

Dog 44  
0.045 fl oz  
Lot #

**FRONTLINE<sup>Plus</sup>**

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

Dog 44  
0.045 fl oz  
Lot #

**FRONTLINE<sup>Plus</sup>**

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

Dog 88  
0.091 fl oz  
Lot #

**FRONTLINE<sup>Plus</sup>**

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

Dog 88  
0.091 fl oz  
Lot #

**FRONTLINE<sup>Plus</sup>**

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

Dog 88  
0.091 fl oz  
Lot #

**FRONTLINE<sup>Plus</sup>**

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

Dog 132  
0.136 fl oz  
Lot #

**FRONTLINE<sup>Plus</sup>**

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

Dog 132  
0.136 fl oz  
Lot #

**FRONTLINE<sup>Plus</sup>**

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

Dog 132  
0.136 fl oz  
Lot #

