

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

	United States	<input type="checkbox"/> Registration	OPP Identifier Number
	Environmental Protection Agency	<input type="checkbox"/> Amendment	
	Washington, DC 20460	<input checked="" type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company/Product Number 65331-5	2. EPA Product Manager Mr. Marion Johnson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Frontline Plus for Dogs	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) Merial Limited 3239 Satellite Blvd. Duluth, GA 30096 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	<b>NOTIFICATION</b> JAN 27 2003
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION Per PR-Notice 2001-6 (Disposal Statements) for changes to the Master Label. This notification is consistent with the guidance in PR Notice 2001-6 and the requirements of EPA's regulations at 40 CFR 156.10 and 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula (CSF) of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the guidance of PR-Notice 2001-6 and the requirements of 40 CFR 156.10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. 6 oz.	No. per container 3 and 6	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.023, 0.045, 0.091 and 0.136 fl. oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other Printed		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Timothy A. Dotson	Title Technical Director	Telephone No. (Include Area Code) 678-638-3713
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  (Stamped)
Signature 	3. Title Technical Director	
4. Typed Name Timothy A. Dotson	5. Date 1/13/03	

2713



**Timothy A. Dotson**  
Technical Director  
Regulatory Affairs North America  
Tel: 678-638-3713  
Fax: 678-638-3715

3239 Satellite Blvd.  
Duluth, GA 30096  
Tel: 678 638 3000

January 13, 2003

Ms. Ann Sibold  
Team 3, Insecticide Branch  
Registration Division (H7505C)  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs  
Room 266A, Crystal Mall #2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

**SUBJECT:** Frontline® Top Spot® for Cats, EPA Reg. No. 65331-2  
Frontline® Top Spot® for Dogs, EPA Reg. No. 65331-3  
Frontline® Plus for Cats, EPA Reg. No. 65331-4  
Frontline® Plus for Dogs, EPA Reg. No. 65331-5  
NOTIFICATION of Label Revisions Per PR-Notice 2001-6

Dear Ms. Sibold:

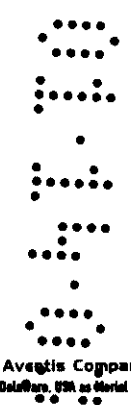
Please find enclosed a NOTIFICATION per PR-Notice 2001-6 for revision of pesticide disposal statements for the aforementioned Frontline® products. Since Merial chose to adopt the exact wording set forth in this notice, the Master labels are being submitted by NOTIFICATION only. Enclosed are copies of EPA Form 8570-1 along with a highlighted copy of the revised Master labels for the 3X/6X pipette presentations for cats/dogs including all four weight range presentations (dogs only). Please note the printed facsimile labels may not be actual size.

Thank you for your assistance. Please call me at 678-638-3713 (email at timothy.dotson@merial.com) if you have any questions regarding this submission.

Sincerely,

Timothy A. Dotson  
Technical Director  
Regulatory Affairs NA

www.merial.com



• Registered Trademark of Merial Ltd.

NOTIFICATION  
JAN 27 2003

**FRONTLINE**  
*Plus*  
for dogs  
For Dogs & Puppies 8 weeks or older and 11-22 lbs.  
For Dogs 23-44 lbs.  
For Dogs 45-88 lbs.  
For Dogs 89-132 lbs.  
**3(6)**

# FRONTLINE®

**3(6)**  
Applicators

**Kills fleas, flea eggs & ticks**

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

**For Dogs & Puppies 8 weeks or older and 11-22 lbs.**

**For Dogs 23-44 lbs.**

**For Dogs 45-88 lbs.**

**For Dogs 89-132 lbs.**

**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**

- 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

*Plus*  
for dogs



MERIAL

(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 and ticks for (dogs and puppies 8 weeks or older and 11-22 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**
- **Prevents and controls reinfestations**
- **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 and ticks.



Adult Flea



Flea Eggs



Flea Larvae



Flea Pupae



Brown Dog Tick



Lone Star Tick



Deer Tick



American Dog Tick

6 8 13

3(6)

For Dogs & Puppies 8 weeks or older and 11-22 lbs.  
For Dogs 23-44 lbs.  
For Dogs 45-88 lbs.  
For Dogs 89-132 lbs.

FRONTLINE<sup>®</sup> Plus for dogs

3(6)

# FRONTLINE<sup>®</sup> Plus for dogs



**FRONTLINE PLUS FOR DOGS** provides fast, effective and convenient treatment and control of fleas and ticks for (dogs and puppies 8 weeks or older and 11-22 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.**

If you are not satisfied with FRONTLINE PLUS 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.

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 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.

### Frequency Of Application

When used monthly, FRONTLINE PLUS FOR DOGS completely breaks the flea life cycle and controls tick 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. FRONTLINE PLUS kills ticks for at least one month. A once monthly application is recommended where tick control is needed. 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 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.

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. 74720-DEU-1)  
(EPA Est. 74528-CHE-1)  
(EPA Est. XXXXX-XXX-X)



LOT NO :

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©2001 Merial. All rights reserved.

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 and ticks.

**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 and ticks 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
- Prevents and controls reinfestations
- 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 and ticks.

**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 and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease), 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.



037 XXXXX

**FREQUENCY OF APPLICATION**

When used monthly, FRONTLINE® PLUS FOR DOGS completely breaks the flea life cycle and controls tick 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. FRONTLINE® PLUS kills ticks for at least one month. A once monthly application is recommended where tick control is needed. 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 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. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant, or nursing 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 11-22 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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# FRONTLINE<sup>®</sup> for dogs

"Flea and Tick Protection Card" *Plus*

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

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<sup>®</sup> PLUS FOR DOGS.

037811034



Remove the adhesive backing and attach to your refrigerator door

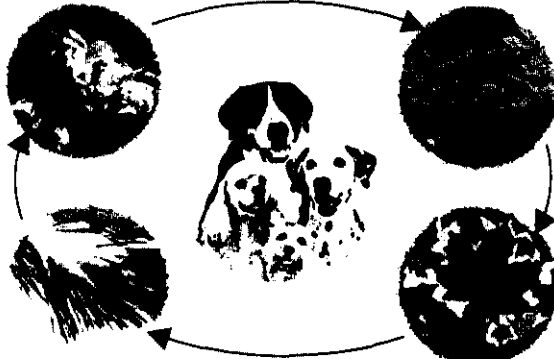
**Fleas and ticks can be a year-round problem!**

**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 and Tick 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.



10 8 13

# FRONTLINE<sup>®</sup> for dogs

## Plus

"Flea and Tick Protection Card"







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

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

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

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<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 PLUS FOR DOGS.

037 81168

Remove the adhesive backing and attach to your refrigerator door

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

**Spring**

*Fleas and ticks breed more frequently as spring progresses.*

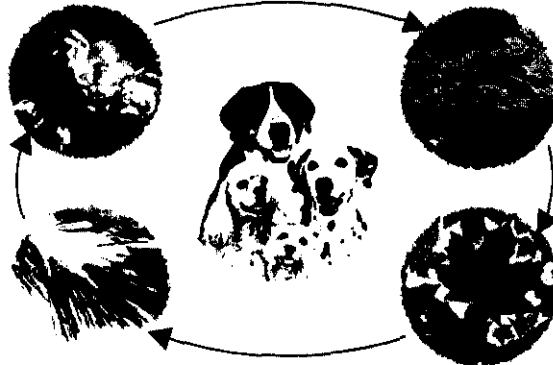
**Summer**

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

**Flea and Tick 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.




**Winter**

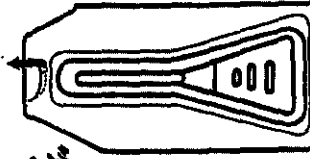
*Minimize the risk of any reinfestation.*

**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.*




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

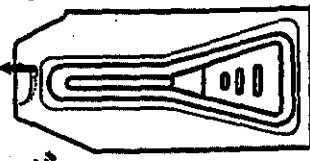


**TO REMOVE APPLICATOR:**  
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.

Dog 44  
0.045 fl oz  
Lot #

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

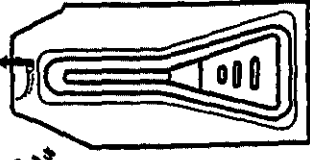


**TO REMOVE APPLICATOR:**  
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.

Dog 44  
0.045 fl oz  
Lot #


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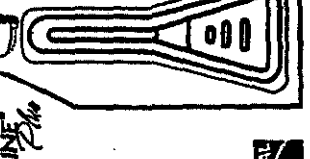
**FRONTLINE<sup>Plus</sup>** 



**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>** 

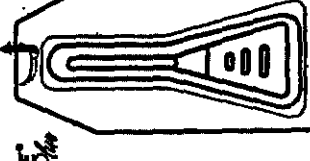


**TO REMOVE APPLICATOR:**  
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.

Dog 132  
0.136 fl oz  
Lot #

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

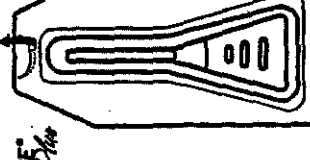


**TO REMOVE APPLICATOR:**  
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.

Dog 132  
0.136 fl oz  
Lot #


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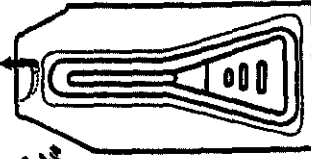
**FRONTLINE<sup>Plus</sup>** 



**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>** 

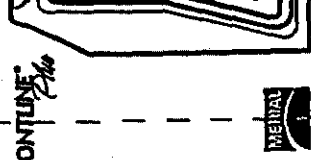


**TO REMOVE APPLICATOR:**  
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.

Dog 22  
0.023 fl oz  
Lot #

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

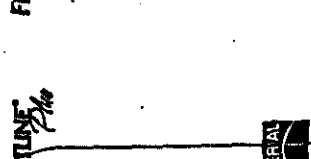


**TO REMOVE APPLICATOR:**  
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.

Dog 22  
0.023 fl oz  
Lot #


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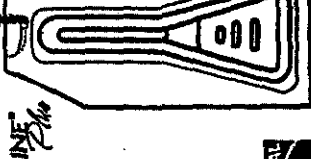
**FRONTLINE<sup>Plus</sup>** 



**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>** 

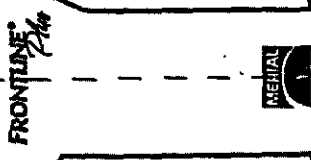


**TO REMOVE APPLICATOR:**  
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.

Dog 88  
0.091 fl oz  
Lot #

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

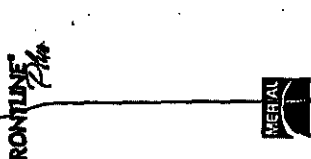


**TO REMOVE APPLICATOR:**  
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.

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 #

Blister Package

