

65331-4

10-24-2003

4/12



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 Plus for Cats
EPA Reg. No. 65331-4
Submission dated 6/19/03

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.

Revise the mosquito kill claim to read as follows:

With a monthly application, Frontline Plus for cats kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 28 days.

Delete references to mosquito "infestations" on cats. Mosquitoes do not infest cats 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,

for Ann Sibold

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

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**ACCEPTED
with COMMENTS
In EPA Letter Dated:
OCT 24 2003**

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
65331-4**



FRONTLINE®
Plus
for cats

For Cats & Kittens
8 weeks or older

3(6)

FRONTLINE®

3(6)
Applicators

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

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

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

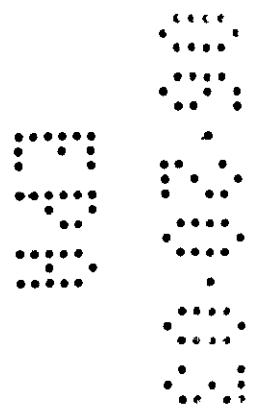
ACTIVE INGREDIENTS	
fipronil.....	9.8%
(S)-methoprene.....	11.8%
INERT INGREDIENTS.....	78.4%
TOTAL.....	100.0%

**KEEP OUT OF
REACH OF CHILDREN
CAUTION**

Contains 3 (6)-0.017 fl oz
(0.50 ml) applicators

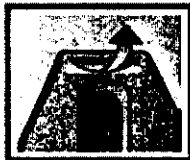
Plus
for cats

(Prototype Graphics)



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How to Apply **FRONTLINE[®]** *Plus* for cats



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.

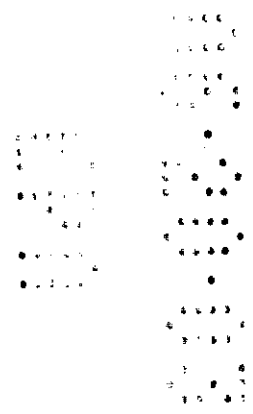


3. Apply FRONTLINE[®] PLUS FOR CATS
Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin.

INSERT COVER TAB HERE

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



4/12

FRONTLINE[®] Plus for cats

FRONTLINE PLUS FOR CATS provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes for cats and kittens 8 weeks or older.

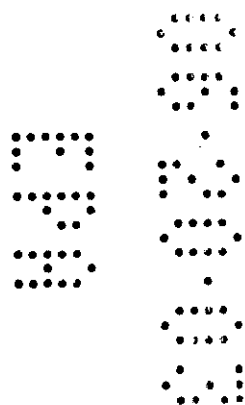
- **Stops and prevents infestations**
- **Kills adult fleas, flea eggs & flea larvae**
- **Prevents all flea stages (eggs, larvae, pupae) from developing**
- **Kills fleas which may cause flea allergy dermatitis**
- **Kills all stages of deer ticks (which may carry Lyme disease), brown dog ticks, American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

FRONTLINE PLUS FOR CATS 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, chewing lice and mosquitoes.



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

XXXXXX 836



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

FRONTLINE Plus for cats

3(6)

FRONTLINE[®] Plus for cats

FRONTLINE PLUS FOR CATS provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes for cats and kittens 8 weeks or older.

Directions For Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.**

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, deer ticks (which may carry Lyme disease), chewing lice and mosquitoes, apply to cats and kittens (8 weeks or older) as follows: Remove applicator from child-resistant package. Hold applicator upright and snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one applicator per treatment is needed.

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

Frequency Of Application

When used monthly, FRONTLINE PLUS FOR CATS completely breaks the flea life cycle and controls tick, chewing lice and mosquito infestations. Research demonstrates that FRONTLINE PLUS kills adult fleas, flea eggs, and flea larvae for up to six weeks. FRONTLINE PLUS also prevents development of all flea stages for up to six weeks. FRONTLINE PLUS kills ticks and mosquitoes for at least one month. A once monthly application is recommended where tick and mosquito control is needed. Although FRONTLINE PLUS can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

FRONTLINE 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. 65331-4
EPA Est. 65331-FR-2
(EPA Est. 65331-DEU-1)
(EPA Est. 65331-GA-1)
(EPA Est. XXXXX-XXX-X)

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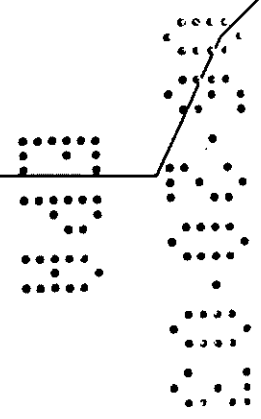
Please call our experts at 1-800-660-1842 if you have any questions or comments about flea, tick, lice and mosquito control or FRONTLINE PLUS.

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



FRONT

FRONTLINE® Plus for cats

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

ACTIVE INGREDIENTS

fipronil:	9.8%
(S)-methoprene	11.8%
INERT INGREDIENTS	78.4%
TOTAL	100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

FRONTLINE® PLUS FOR CATS provides fast, effective and
convenient treatment and control of fleas, ticks, chewing
lice and mosquitoes for cats and kittens.

- 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
- Can also be used on breeding, pregnant and lactating queens
- Fast-acting
- Long-lasting
- Waterproof
- Convenient to use

FRONTLINE® PLUS FOR CATS 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, chewing lice and mosquitoes.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner
inconsistent with its labeling. Do not allow children to apply
product. **TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.**

To kill fleas, all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (which may carry Lyme disease), chewing lice and mosquitoes, apply to cats and kittens (8 weeks or older) as follows:

Remove applicator from child-resistant package. Hold applicator upright and snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one applicator per treatment is needed.



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BACK

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

FREQUENCY OF APPLICATION

When used monthly, FRONTLINE® PLUS FOR CATS completely
breaks the flea life cycle and controls tick, chewing lice
and mosquito infestations. Research demonstrates that
FRONTLINE® PLUS kills adult fleas, flea eggs, and flea
larvae for up to six weeks. FRONTLINE® PLUS also prevents
development of all flea stages for up to six weeks. FRONTLINE®
PLUS kills ticks and mosquitoes 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 six weeks, if there is a high risk of reinfestation
or if the pet has fleas which may cause flea allergy dermatitis,
a once monthly application may be needed.

FRONTLINE® PLUS FOR CATS 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 kittens under 8 weeks
of age. Individual sensitivities, while rare, may occur after
using any pesticide product. Pets may experience some
temporary irritation at the site of product application. If signs
persist, or become more severe within a few days of application,
consult a veterinarian immediately. Certain medications can
interact with pesticides. Consult a veterinarian before
using on medicated, debilitated or aged animals.
Call 1-800-660-1842 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

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

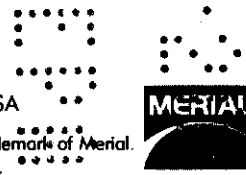
WARRANTY

Seller makes no warranty, expressed or implied, concerning
the use of this product other than indicated on the label.
Buyer assumes all risk of use and handling of this material
when such use and handling are contrary to label instructions.

EPA Reg. No. 65331-4

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

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CATS compliance card x3 - Front

FRONTLINE[®] for cats

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

Plus

Apply FRONTLINE[®] PLUS FOR CATS monthly, or as needed, for continuous protection against fleas, ticks, chewing lice and mosquitoes.

Pet's Name:

Date of first treatment:

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Month 1

Month 2

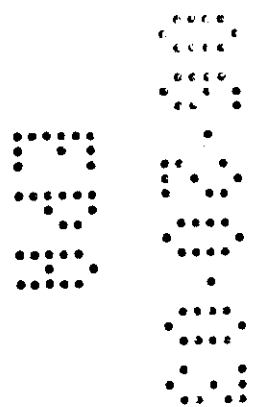
Month 3



Place stickers on calendar as a reminder to apply FRONTLINE[®] PLUS FOR CATS.

001 000000X

(Prototype Graphics)



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CATS compliance card x3 - Back

Remove the adhesive backing and attach to your refrigerator door

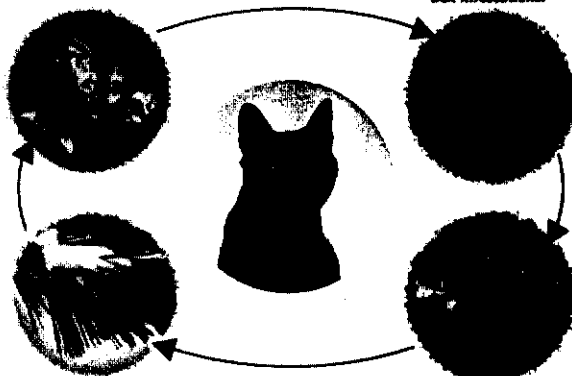
Fleas, Ticks, Chewing Lice and Mosquitoes can be a year-round problem

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.

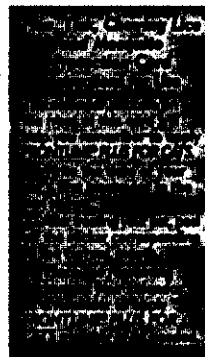


Winter

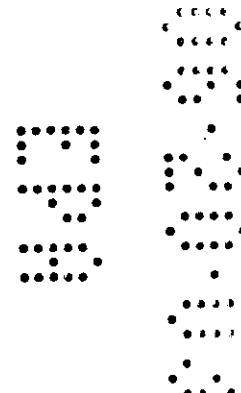
Minimize the risk of any reinfestation.

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.



(Prototype Graphics)




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CATS compliance card x6 - Front




FRONTLINE[®] *Plus* for cats
 "Flea, Tick, Chewing Lice and Mosquito Protection Card"

Apply FRONTLINE PLUS FOR CATS monthly, or as needed, for continuous protection against fleas, ticks, chewing lice and mosquitoes.




Pet's Name: _____ Date of first treatment: _____



Month 1 Month 2 Month 3

Month 4 Month 5 Month 6

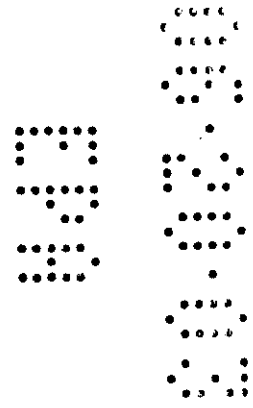




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Place stickers on calendar as a reminder to apply FRONTLINE PLUS FOR CATS.

007 200000X

(Prototype Graphics)



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CATS compliance card x6 - Back

Remove the adhesive backing and attach to your refrigerator door

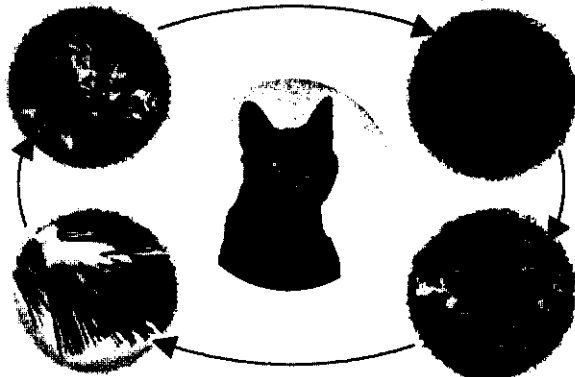
Fleas, Ticks, Chewing Lice and Mosquitoes can be a year-round threat!

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.

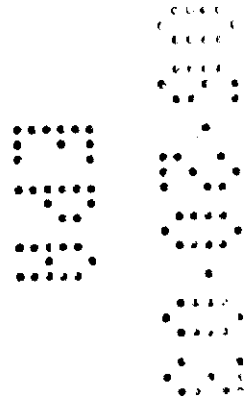
Fleas, Ticks, Chewing Lice and Mosquito Protection Card
 Important for Linc

No chemical residues on the front of this card will help you remember to apply FRONTLINE PLUS FOR CATS. With the help of your veterinarian, you can keep your cat safe from fleas, ticks, chewing lice and mosquitoes.

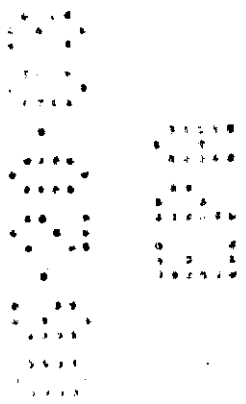
After leaving your pet, put off the sticker corresponding to the season you're in. Place the sticker on your pet's collar. It's recommended to apply FRONTLINE PLUS FOR CATS monthly as directed.



(Prototype Graphics)



2/1/12



FRONTLINE ^{Plus}		Merial	<p>TO REMOVE APPLICATOR: Use scissors. Or lift and remove plastic tab to expose foil, then peel down.</p>	<p>Cat 0.017 fl oz Lot #</p>
FRONTLINE ^{Plus}		Merial	<p>TO REMOVE APPLICATOR: Use scissors. Or lift and remove plastic tab to expose foil, then peel down.</p>	<p>Cat 0.017 fl oz Lot #</p>
FRONTLINE ^{Plus}		Merial	<p>TO REMOVE APPLICATOR: Use scissors. Or lift and remove plastic tab to expose foil, then peel down.</p>	<p>Cat 0.017 fl oz Lot #</p>
FRONTLINE ^{Plus}		Merial	<p>TO REMOVE APPLICATOR: Use scissors. Or lift and remove plastic tab to expose foil, then peel down.</p>	<p>Cat 0.017 fl oz Lot #</p>

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