

65331-2

2/12/2013

1/22



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

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION PREVENTION

February 12, 2013

Ms. Karen Mardis  
Senior Manager, Regulatory Affairs  
Merial Limited  
3239 Satellite Blvd. Building 500, Office 113  
Duluth, GA 30096-4640

Subject: Notification for Minor label Change  
EPA Registration Number: 65331-2  
Decision: 473827

Dear Ms. Mardis:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration (PRN) 98-10 dated December 20, 2012, for the abovementioned product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions regarding this letter, please contact Driss Benmhend at (703) 308-9525.

Sincerely,

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

Richard J. Gebken  
Product Manager (10)  
Insecticide Branch  
Registration Division (7504P)

Enclosures: Copy of Label Stamped "Notification"

Please read instructions on reverse before completing form.

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



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 65331-2	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restrictive
4. Company/Product (Name) Frontline Top Spot For Cats	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Merial Limited 3239 Satellite Blvd., Bld. 500 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 _____
<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.)

Change in primary Brand Name and deletion of website information per PR Notice 98-10

Section - III

1. Material This Product Will Be Packaged In:

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"/> Text	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. 6 oz. No. per container 1,3,or 6	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container	4. Size(s) Retail Container 0.017 fl. oz.	5. Location of Label Directions <input type="checkbox"/> On Label <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 checked="" type="checkbox"/> Other Label insert

Section - IV

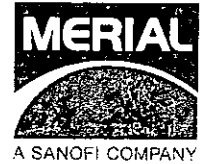
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Karen Mardis	Title Senior Manager, Regulatory Affairs	Telephone No. (Include Area Code) 678-638-3706
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Certification 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)
2. Signature 	3. Title Senior Manager, Regulatory Affairs	
4. Typed Name Karen Mardis	5. Date December 20, 2012	

3/2

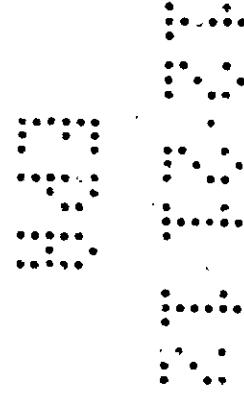
**Karen Mardis**  
Senior Manager, Regulatory Affairs North America  
Tel: 678-638-3706  
Fax: 678-638-3707  
[karen.mardis@merial.com](mailto:karen.mardis@merial.com)



3239 Satellite Blvd  
Duluth, GA 30096  
Tel: 678.638.3000

December 20, 2012

Richard Gebken, Product Manager 10  
Registration Division  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501



**SUBJECT:** Change in Primary Brand Name

Frontline® Top Spot® for Cats: EPA Reg. No. 65331-2  
Frontline Top Spot for Dogs: EPA Reg. No. 65331-3

Dear Mr. Gebken:

Merial hereby submits the following notification to change the primary brand name of the above mentioned products to FIPAIRA™ for Cats (EPA Reg. No. 65331-2) and FIPAIRA for Dogs (EPA Reg. No. 65331-3). To that end please find attached:

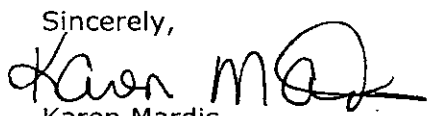
- A completed application (EPA Form 8570-1) for each product
- 1 copy of labeling for each product

Please note that the labeling provided does not yet include all of the mitigation actions identified in the Agency's Pet Spot-On Mitigation Plan. Merial's submission of September 20, 2012 regarding specific points of the mitigation plan is still under review at the agency. Merial will update the labeling, as appropriate, once an agreement on these items has been reached.

Additionally the following non-FIFRA information was deleted from the labeling: website information for [www.Frontline.com](http://www.Frontline.com).

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula 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 is this notification is not consistent with the terms of PR Notice 98-10 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.

If you have any questions or require additional information, please contact me by telephone at 678-638-3138 or email at [Karen.Mardis@Merial.com](mailto:Karen.Mardis@Merial.com).

Sincerely,  
  
Karen Mardis

www.merial.com

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Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

**Master Label**  
**1x, 3x and 6x presentations**

[Optional text appears in brackets – the final product label may include some or all of the optional text on the front, back, or side panels.]

**FIPAIRA™ FOR CATS**

(FRONT PANEL OF 3X and 6X CARTON)

**FIPAIRA™ FOR CATS**

**[3][6] doses**

Picture of pipette

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

- Fast-acting
- Long-lasting
- Waterproof

Picture of Cat

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

For use ONLY on CATS & KITTENS **8 Weeks and Older.**

**ACTIVE INGREDIENT:**

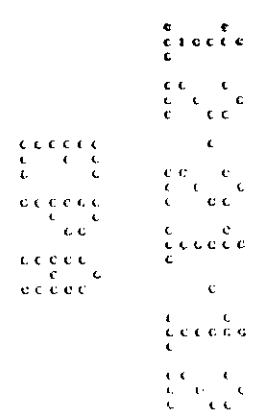
Fipronil.....9.7%  
 INERT INGREDIENTS.....90.3%  
 TOTAL.....100%

**NOTIFICATION**  
**FEB 12 2013**

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

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

**CAUTION**



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Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

(LEFT INNER PANEL OF 3X and 6X CARTON)

**FIPAIRA™ FOR CATS**

**FIPAIRA™ for Cats is:**

- Fast-acting
- Long-lasting
- Waterproof

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

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

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

**FIPAIRA for Cats:**

**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, haemobartonellosis and other tick-borne diseases

**Lice**

- Rapidly eliminates chewing lice infestations

**[Mosquitoes]**

- [Kills mosquitoes]

**FIPAIRA** is approved for use on all cats, including:

- Breeding, pregnant, and lactating queens
- Kittens as young as 8 weeks



Adult Fleas



Chewing Lice



Ticks



[Mosquitoes]

6/22

(RIGHT INNER PANEL OF 3X and 6X CARTON)

**How to Apply FIPAIRA™ FOR CATS**



**Step 1. To REMOVE Applicator:**

Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.



**Step 2. OPEN Applicator**

Hold upright with foil side toward you and snap applicator tip.



**Step 3. APPLY FIPAIRA**

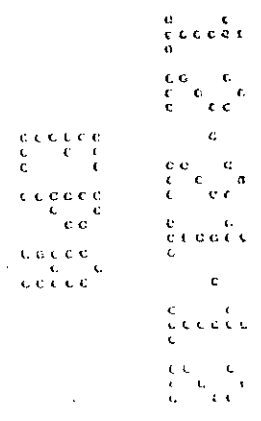
Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cat's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

**Questions or Comments?**

**Call: 1-800-660-1842.**

**Monday-Friday, 8am-8pm EST**

Bar code



Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

7/22

(BACK PANEL OF 3X and 6X CARTON)

### FIPAIRA™ FOR CATS

FIPAIRA for Cats provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, [and] chewing lice [and mosquitoes] for use ONLY on 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, ticks, [and] chewing lice [and mosquitoes] apply FIPAIRA for Cats 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 FIPAIRA. Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cat's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

FIPAIRA for Cats is approved for use on all cats, including breeding, pregnant, and lactating queens and kittens as young as 8 weeks.

FIPAIRA remains effective even after bathing, water immersion, or exposure to sunlight.

#### Frequency of Application

When used monthly, FIPAIRA completely controls flea, tick and chewing lice infestations.

Do not reapply FIPAIRA for 30 days.

FIPAIRA kills adult fleas for up to six weeks, however, if there is a high risk of reinfestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

FIPAIRA kills ticks for at least one month. A once monthly application is recommended where tick control is needed. FIPAIRA kills all life stages of ticks (larva, nymph and adult).

FIPAIRA kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis, haemobartonellosis and other tick-borne diseases.

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

[FIPAIRA kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 28 days, with a monthly application.]

Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

(BACK PANEL OF 3X and 6X CARTON - CONT.)



Please call our experts at **1-800-660-1842**, Monday-Friday, 8am-8pm EST, with any questions or comments about flea, tick, [or] chewing lice, [or mosquito] control or FIPAIRA.



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

™ FIPAIRA is a trademark of Merial.  
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© 2012 Merial Limited  
Duluth, GA 30096-4640  
USA  
MADE IN FRANCE



a/  
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Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

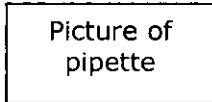
Notification

(TOP OUTER PANEL and LEFT SIDE OUTER PANEL OF 3X and 6X CARTON)

**FIPAIRA™ FOR CATS**

For use ONLY on CATS & KITTENS 8 Weeks and Older

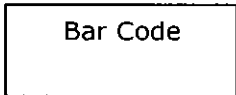
**[3][6] doses**



Picture of  
pipette

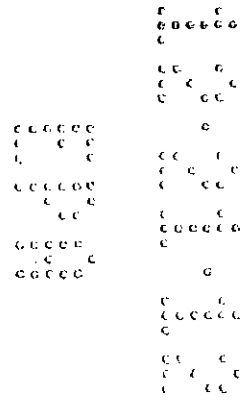
[BOTTOM OUTER PANEL OF 3X and 6X CARTON]

For cat use only



Bar Code

(RIGHT SIDE OUTER PANEL OF 3X and 6X CARTON)



EPA Reg. No 65331-2    LOT NO:

EPA Est.

Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

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(INSERT FOR 3X AND 6X)

**FIPAIRA™ FOR CATS**

**For use ONLY on CATS & KITTENS 8 weeks or older:  
Fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, [and]  
chewing lice [and mosquitoes].**

**ACTIVE INGREDIENT**

fipronil ..... 9.7%

**INERT INGREDIENTS.....90.3%**

**TOTAL .....100%**

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**FIPAIRA™ for Cats:**

**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, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases

**Lice**

- Rapidly eliminates chewing lice infestations

**[Mosquitoes]**

- [Kills mosquitoes]

**FIPAIRA is approved for use on all cats, including:**

- Breeding, pregnant, and lactating queens
- Kittens as young as 8 weeks

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

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

Fleas, ticks, and chewing lice are killed quickly after coming into contact with a treated cat. Fleas and ticks do not need to bite the cat 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 CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

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(INSERT FOR 3X AND 6X - CONT.)

To kill fleas, ticks, [and] chewing lice [and mosquitoes] apply FIPAIRA for Cats 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* FIPAIRA

Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cat's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

FIPAIRA for Cats is approved for use on all cats, including breeding, pregnant, and lactating queens and kittens as young as 8 weeks.

FIPAIRA remains effective even after bathing, water immersion, or exposure to sunlight.

**FREQUENCY OF APPLICATION**

When used monthly, FIPAIRA completely controls flea, tick and chewing lice infestations. Do not reapply FIPAIRA for 30 days.

FIPAIRA kills adult fleas for up to six weeks, however, if there is a high risk of reinfestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

FIPAIRA kills ticks for at least one month. A once monthly application is recommended where tick control is needed.

FIPAIRA kills all life stages of ticks (larva, nymph and adult). FIPAIRA kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

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

[FIPAIRA kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 23 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.

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Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

(INSERT FOR 3X AND 6X - CONT.)

**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 or 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 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, Monday-Friday, 8am-8pm EST.

**PHYSICAL OR CHEMICAL HAZARDS**

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

**WARRANTY**

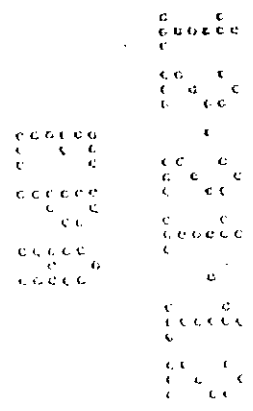
To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions.

EPA Reg. No. 65331-2

**Merial Limited**

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

<sup>TM</sup> FIPAIRA is a trademark of Merial.  
©2012 Merial Limited, Duluth, GA.  
All rights reserved.



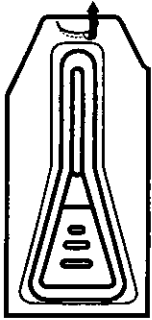
Bar Code

Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

(3X and 6X Back of Blister)

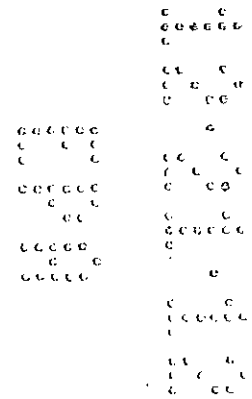
FIPAIRA™



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

0.017 fl oz  
Lot #

**CAT**



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Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

(1X, 3X, 6X PIPETTE)

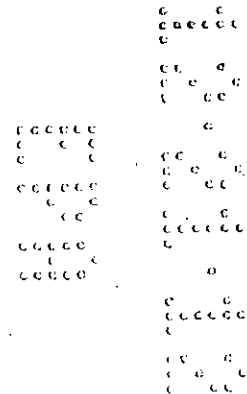
MERIAL  
Contains fipronil (9.7%)



0.017 fl oz  
**FIPAIRA™**

Keep out of reach of children  
See full label for additional directions

**CAUTION**  
EPA Reg. No. 65331-2



Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

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(3X AND 6X COMPLIANCE CARD - FRONT)

**FIPAIRA™**

See other side for more...



**Fleas**



**Ticks**



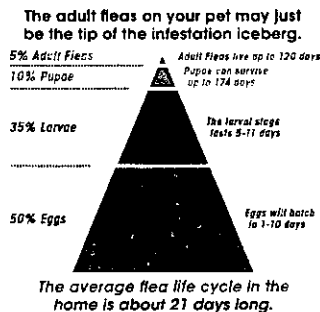
**Chewing Lice**

Some tips and other information

- To successfully control fleas and ticks, all dogs and cats must be treated with their own dose of FIPAIRA™.
- 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 FIPAIRA 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 FIPAIRA.



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Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

(3X AND 6X COMPLIANCE CARD - BACK)

Calendar Reminder Stickers

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

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

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

Don't forget to re-purchase!

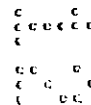
**QUESTIONS?**

Contact your veterinarian or call our technical experts at **1-800-660-1842**.  
Monday-Friday, 8am-8pm.

™ FIPAIRA is a trademark of Merial.  
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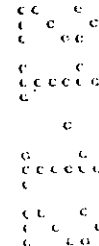
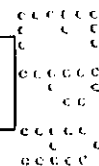
**6 Months**  
use all 6 stickers

3 stickers that read "Apply FIPAIRA™"  
with a picture of a pipette



**3 Months**

3 stickers that read "Apply FIPAIRA™"  
with a picture of a pipette



Bar Code



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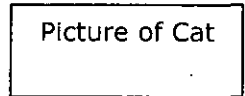
Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

(FRONT PANEL OF 1X Insert)



**FIPAIRA™ FOR CATS**



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

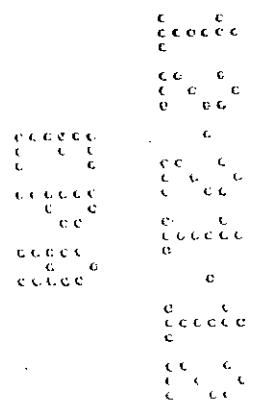
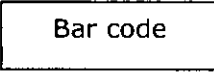
**Kills fleas, ticks, [&] chewing lice [& mosquitoes]**

- Fast-acting
- Long-lasting
- Waterproof

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

Contains 1-0.017 fl oz (0.50 ml) applicator  
**1 monthly dose**

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



For use ONLY on CATS & KITTENS **8 weeks and Older.**

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

**CAUTION**

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Reason to issue: Change Brand Name  
EPA Reg. No. 65331-2  
Information in [ ] is optional.  
November 26, 2012

Notification

(INNER PANELS FOR 1X INSERT)

**FIPAIRA™ FOR CATS**

**For use ONLY on CATS & KITTENS 8 weeks or older:  
Fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, [and]  
chewing lice [and mosquitoes].**

**ACTIVE INGREDIENT**

fipronil ..... 9.7%

**INERT INGREDIENTS.....90.3%**

**TOTAL .....100%**

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**FIPAIRA™ for Cats:**

**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, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases

**Lice**

- Rapidly eliminates chewing lice infestations

**[Mosquitoes]**

- [Kills mosquitoes]

**FIPAIRA is approved for use on all cats, including:**

- Breeding, pregnant, and lactating queens
- Kittens as young as 8 weeks

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

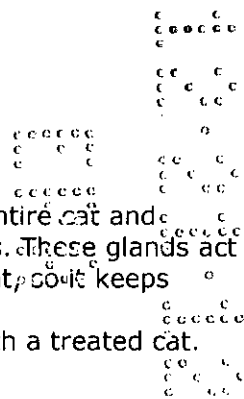
FIPAIRA spreads from the single point of application, rapidly covering the entire cat and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing FIPAIRA onto the skin and hair coat, so it keeps working even if the cat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

Fleas, ticks, and chewing lice are killed quickly after coming into contact with a treated cat.

Fleas and ticks do not need to bite the cat 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 CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.



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(INNER PANELS FOR 1X INSERT - CONT.)

To kill fleas, ticks, [and] chewing lice [and mosquitoes] apply FIPAIRA for Cats as follows:

• **OPEN** Applicator

Hold upright with foil side toward you and snap applicator tip.

• **APPLY** FIPAIRA

Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cat's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

FIPAIRA for Cats is approved for use on all cats, including breeding, pregnant, and lactating queens and kittens as young as 8 weeks.

FIPAIRA remains effective even after bathing, water immersion, or exposure to sunlight.

**FREQUENCY OF APPLICATION**

When used monthly, FIPAIRA completely controls flea, tick and chewing lice infestations. Do not reapply FIPAIRA for 30 days.

FIPAIRA kills adult fleas for up to six weeks, however, if there is a high risk of reinfestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

FIPAIRA kills ticks for at least one month. A once monthly application is recommended where tick control is needed.

FIPAIRA kills all life stages of ticks (larva, nymph and adult). FIPAIRA kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

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

[FIPAIRA kills mosquitoes within 24 hours for up to 14 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 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.

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Reason to issue: Change Brand Name  
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(INNER PANELS FOR 1X INSERT - CONT.)

**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 or advice.

**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 and before eating, drinking, chewing gum, or using tobacco.

**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, Monday-Friday, 8am-8pm EST.

**PHYSICAL OR CHEMICAL HAZARDS**

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

**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.  
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(BACK PANEL OF 1X Insert)

**How to Apply FIPAIRA™ FOR CATS**



**Step 1.  
OPEN Applicator**

Hold upright with foil side toward you and snap applicator tip.

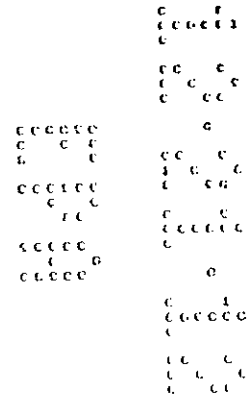


**Step 2.  
APPLY FIPAIRA**

Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cat'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**

Bar Code



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Reason to issue: Change Brand Name  
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Information in [ ] is optional.  
November 26, 2012

Notification

(1X Back of Blister)

