

65331-3

2/5/2013

1/22



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

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 5, 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: 65331-3
Decision: 473826

Dear Ms. Huebl:

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".

for, 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 2-25



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 65331-3	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 Dogs	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

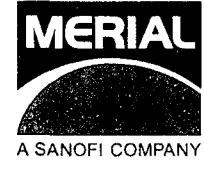
Section - III

1. Material This Product Will Be Packaged In:				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"/> Text <input 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 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 0.023, 0.045, 0.091 and 0.136 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 Printed	

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
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	

3/22



Karen Mardis
Senior Manager, Regulatory Affairs North America
Tel: 678-638-3706
Fax: 678-638-3707
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:

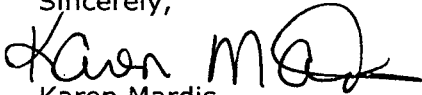
- A completed application (EPA Form 8570-1) for each product
- ~~3~~ ¹ copies of labeling for each product

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.

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.

Sincerely,

Karen Mardis

www.merial.com

4/22

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

Master Label
1x, 3x and 6x presentations

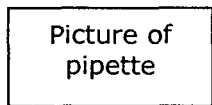
[Optional text appears in brackets – the final product label may include some or all of the optional text on the front, back, or side panels.]

FIPAIRA™ FOR DOGS

(FRONT PANEL OF 3X and 6X CARTON)

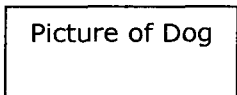
FIPAIRA™ FOR DOGS

[3][6] doses



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

- Fast-acting
- Long-lasting
- Waterproof



Kills ticks, including those that may transmit Lyme disease

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

NOTIFICATION

FEB - 5 2013

ACTIVE INGREDIENTS:
 Fipronil.....9.7%
 INERT INGREDIENTS.....90.3%
 TOTAL100%

[Contains [3][6]-0.023 fl oz (0.67 ml) applicators]
 [Contains [3][6]-0.045 fl oz (1.34 ml) applicators]
 [Contains [3][6]-0.091 fl oz (2.68 ml) applicators]
 [Contains [3][6]-0.136 fl oz (4.02 ml) applicators]

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

CAUTION

5/22

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

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

FIPAIRA™ FOR DOGS

FIPAIRA™ for Dogs is:

- Fast-acting
- Long-lasting
- Waterproof

One spot application is all that's needed:

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

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

FIPAIRA for Dogs:

Fleas

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

Ticks

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

Lice

- Rapidly eliminates chewing lice infestations

[Mosquitoes]

- [Kills mosquitoes]

Mites

- Aids in the control of sarcoptic mange infestations

FIPAIRA is approved for use on all dogs, including:

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



Adult Fleas



Chewing Lice



Ticks



[Mosquitoes]

6/22

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

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

How to Apply FIPAIRA™ FOR DOGS

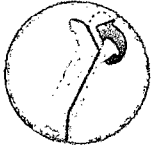
Step 1. To REMOVE Applicator:

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 dog'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 dog's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.



Questions or Comments?

Call: 1-800-660-1842.

Monday-Friday, 8am-8pm EST

Bar Code

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

(BACK PANEL OF 3X and 6X CARTON)

FIPAIRA™ FOR DOGS

FIPAIRA for Dogs provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice, [and] sarcoptic mites [and mosquitoes] for use ONLY on [dogs and puppies 8 weeks or older and up to 22 lbs.][dogs weighing 23-44 lbs.][dogs weighing 45-88 lbs.][dogs weighing 89-132 lbs.].

Directions for Use

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

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

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

FIPAIRA is approved for use on breeding, pregnant, and lactating bitches and puppies 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 three months, however, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

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 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 aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

[FIPAIRA kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days, with a monthly application.]

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Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
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, chewing lice, [or] sarcoptic mite [or mosquito] control or FIPAIRA.



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

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9/22

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

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

FIPAIRA™ FOR DOGS

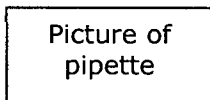
[For use ONLY on DOGS & PUPPIES 8 Weeks or Older and up to **22lbs**]

[For use ONLY on DOGS **23 to 44lbs**]

[For use ONLY on DOGS **45 to 88lbs**]

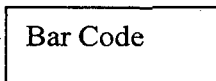
[For use ONLY on DOGS **89 to 132lbs**]

[3][6] doses



(BOTTOM OUTER PANEL OF 3X and 6X CARTON)

For dog use only



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

EPA Reg. No 65331-3 LOT NO:

EPA Est.

10/22

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

(INSERT FOR 3X AND 6X)

FIPAIRA™ FOR DOGS

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

ACTIVE INGREDIENT

fipronil 9.7%
INERT INGREDIENTS.....90.3%
TOTAL100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIPAIRA™ for Dogs:

Fleas

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

Ticks

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

Lice

- Rapidly eliminates chewing lice infestations

Mites

- Aids in the control of sarcoptic mange infestations

[Mosquitoes]

- [Kills mosquitoes]

FIPAIRA is approved for use on all dogs, including:

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

One spot application is all that's needed:

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

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

Fleas and ticks do not need to bite the dog in order to die.

DIRECTIONS FOR USE

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

11/22

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

(INSERT FOR 3X AND 6X – CONT.)

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

- To REMOVE Applicator: Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.
- OPEN Applicator.
Hold upright with foil side toward you and snap applicator tip.
- APPLY FIPAIRA

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

FIPAIRA for Dogs is approved for use on breeding, pregnant, and lactating bitches and puppies 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 three months, however, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

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 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 aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

[FIPAIRA kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days, with a monthly application.]

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a

12/22

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

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

poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment 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 puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-660-1842, Monday-Friday, 8am-8pm EST.

PHYSICAL OR CHEMICAL HAZARDS

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

HOW SUPPLIED

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

WARRANTY

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

EPA Reg. No. 65331-3

Merial Limited

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

™ FIPAIRA is a trademark of Merial.
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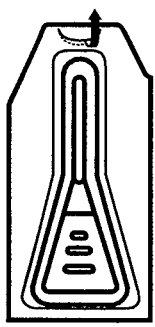
Bar Code

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

(3X and 6X 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.

[0.023 fl oz][0.045 fl oz][0.091 fl oz][0.136 fl oz]
Lot #

DOG [22][44][88][132]

14/22

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

(1X, 3X, 6X PIPETTE)

MERIAL
Contains fipronil (9.7%)



[0.023 fl oz][0.045 fl oz][0.091 fl oz][0.136 fl oz]
FIPAIRA™

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

CAUTION
EPA Reg. No. 65331-3

15/22

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

(3X AND 6X COMPLIANCE CARD – FRONT)

FIPAIRA™

See other side for more...



Fleas



Ticks



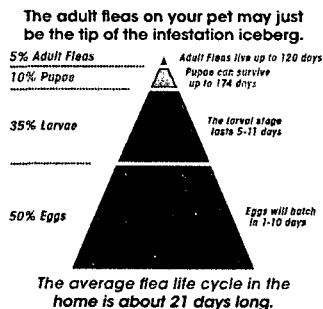
Chewing Lice

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.



16/22

Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
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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Duluth, GA.
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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

17/22

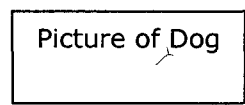
Reason to issue: Change Brand Name
EPA Reg. No. 65331-3
Information in [] is optional.
November 26, 2012

Notification

(FRONT PANEL OF 1X Insert)



FIPAIRA™ FOR DOGS



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

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

- Fast-acting
- Long-lasting
- Waterproof

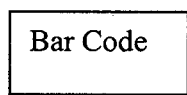
ACTIVE INGREDIENTS:

Fipronil.....9.7%
 INERT INGREDIENTS.....90.3%
 TOTAL100%

- [Contains 1-0.023 fl oz (0.67 ml) applicator]
- [Contains 1-0.045 fl oz (1.34 ml) applicator]
- [Contains 1-0.091 fl oz (2.68 ml) applicator]
- [Contains 1-0.136 fl oz (4.02 ml) applicator]

1 monthly dose

Kills ticks, including those that may transmit Lyme disease



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

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

CAUTION

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Information in [] is optional.
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Notification

(INNER PANELS FOR 1X INSERT)

FIPAIRA™ FOR DOGS

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

ACTIVE INGREDIENT

fipronil	9.7%
INERT INGREDIENTS.....	90.3%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIPAIRA™ for Dogs:

Fleas

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

Ticks

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

Lice

- Rapidly eliminates chewing lice infestations

Mites

- Aids in the control of sarcoptic mange infestations

[Mosquitoes]

- [Kills mosquitoes]

FIPAIRA is approved for use on all dogs, including:

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

One spot application is all that's needed:

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

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

DIRECTIONS FOR USE

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

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(INNER PANELS FOR 1X INSERT – CONT.)

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

- *OPEN* Applicator.

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

- *APPLY* FIPAIRA

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

FIPAIRA for Dogs is approved for use on breeding, pregnant, and lactating bitches and puppies 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 three months, however, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

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 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 aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

[FIPAIRA kills mosquitoes within 24 hours for up to 7 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

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(INNER PANELS FOR 1X INSERT - CONT.)

poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment 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 puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-660-1842, Monday-Friday, 8am-8pm EST.

PHYSICAL OR CHEMICAL HAZARDS

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

HOW SUPPLIED

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

WARRANTY

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

Merial Limited

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

TM FIPAIRA is a trademark of Merial.

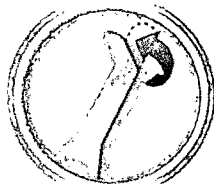
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(BACK PANEL OF 1X Insert)

How to Apply FIPAIRA™ FOR DOGS



Step 1.
OPEN Applicator

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



Step 2.
APPLY FIPAIRA

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

Questions or Comments?

Call: 1-800-660-1842.

Monday-Friday, 8am-8pm EST

Bar Code

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(1X BLISTER)

