

2382-186

01-14-2011

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

2382-186

Date of Issuance:

January 14, 2011

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional
Time limited registration for 2 years

Name of Pesticide Product:

Effipro Topical Solution for Cats

Name and Address of Registrant (include ZIP Code):

Virbac AH, Inc.
3200 Meacham Blvd.
Fort Worth, TX 76137

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

(continued on page 3)

Signature of Approving Official:

Richard J. Gebken, Product Manager (10)
Insecticide Branch, Registration Division (7505P)

Date:

January 14, 2011

2. Make the following change to the label:

1. Change the product registration number to "EPA Reg. No. 2382-186
2. Remove the following tube and respective weight ranges from the product label:
 1. 6 tube count containing 0.5ml for cat.
Additional Child Resistant Packaging data is needed to approve these product sizes.
3. Remove and or modify all label as follows
 - Remove the subheading "PHYSICAL OR CHEMICAL HAZARDS" from all locations, since there is no text associated with this subheading.
 - Within the First Aid section for all locations, change "IF ON SKIN" to "IF ON SKIN OR CLOTHING"
 - Change "However, a monthly application is recommended" in all locations to "Apply monthly"
 - Remove the following statement: "[HOW TO APPLY(?)] " from all locations on the label.
 - Change "pet's" and "pet" in all locations to "cat's" and "cat respectively."
 - Change the word "treatment" to "application" and "treat" to "apply" in all areas of the label.
 - Change "For Cats and Kittens 8 weeks old and older" to "Only for Cats and Kittens 8 weeks old and older" in all locations on the label.
 - Change "For animal use only" in all locations to "For Use on Cats only." All locations on the label.
 - Change "Wash thoroughly with soap and water after handling." Within the Hazards to Humans section of the label (all locations) to "Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco." All locations on the label.
 - The Signal Word "CAUTION" must be in all caps and bold in all locations
 - Change the following statement in all locations from "For killing fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (including those tick vectors which may transmit Lyme disease and other tick borne diseases), mosquitoes and chewing lice; apply to CATS or Kittens (8 weeks old or older) as follows:" by "removing the words **"including those tick vectors"** from the statement. The Agency acknowledges only the standard claim "Deer ticks that may transmit [carry] Lyme disease."
 - Remove the following text from all locations on the label "• Once monthly application" and "X applicators (tubes) X monthly doses (applications) (treatments)" The "X" in these statements is open ended, and is dictated by the CRP studies conducted for each product size and count.
 - In all locations on the label, the "any" must be changed to all caps in the following statement: "Individual sensitivities, while rare, may occur after using any pesticide product."
 - Revise the statement in all locations on the label from: "For animal use only" to For Use on Cats only"

4. Remove the following marketing claims or other conflicting claims:

• :

Virbac **PARASITOLOGY**
ANIMAL HEALTH

- It is not consistent with the name at the bottom of the label for the company. In

addition this product is not intended as an "ANIMAL HEALTH" or "PARISITOLOGY" product.

- Stops existing infestations and prevents establishment of new infestations
- Pest reinfestations prevented for a month or longer
- Kills fleas that may transmit disease, including bartonellosis, tapeworm and tularemia
- Kills all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (ticks that may transmit Lyme disease, Rocky Mountain Spotted fever, babesiosis, ehrlichiosis, anaplasmosis, cytauxzoonosis, and other tick borne diseases)
- Performance guaranteed or (Virbac Animal Health will supply new product) (your money back) (Virbac Animal Health will supply new product or your money back)
- Quick onset of activity
- Fragrance (odor) free
- No noticeable odors
- Rapid kill of fleas is important in the prevention of disease transmission by(these) parasites
- Available from (licensed) veterinarians
- Sold by veterinarians
- Regular use breaks the flea life cycle
- Performance guaranteed or your money back (Please call our professional staff at xxx-xxx-xxxx if you have any questions or comments about EFFIPRO 'TOPICAL SOLUTION FOR CATS)
- Kills fleas that may transmit bartonellosis and tapeworm disease
- Persistent efficacy through 30 days
- Monthly treatment (all year) is recommended for control and prevention of fleas
- X applicators (tubes) X monthly doses (applications) (treatments)
- Available from licensed veterinarians
- Kills fleas that may transmit diseases, including bartonellosis, tapeworm and tularemia
- Acts to kill fleas that may transmit disease, such as bartonellosis, tape worm and tularemia
- Easy to use applicator makes treatment simple (trouble free, smooth) and comfortable for your pet
- Provides ongoing protection against fleas and the diseases they may transmit for one month
- Picture of cat (or kitten)
- Monthly treatment is recommended for control and prevention of fleas, ticks and mosquitoes
- Kills the vectors that may transmit Lyme disease, Rocky Mountain Spotted fever, babesiosis, ehrlichiosis, bartonellosis, cytauxzoonosis and heartworm disease
- Treatment of cats with EFFIPRO® TOPICAL SOLUTION FOR CATS rapidly kills fleas that may cause FAD (flea allergy dermatitis)
- Long lasting flea, tick and mosquito control for your pet
- Remove the Gulf Coast tick from all claims.
- Single application lasts 4 weeks (one month) (30 days)
- Kills fleas that may serve as an intermediate host for tapeworms (Dipylidium caninum)
- Stops existing flea infestations by rapidly killing adult fleas

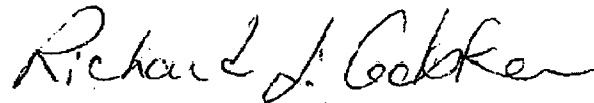
- Illustration of flea life cycle
 - Illustration of tick life cycle
 - Illustration of mosquito life cycle
 - Illustration of mite life cycle
 - Illustration of louse life cycle
 - Illustration of flea
 - Illustration of tick
 - Illustration of mosquito
 - Illustration of mite
 - Illustration of louse
 - Veterinary recommended
 - Veterinarian recommended
 - Chewing lice infestations are rapidly eliminated
 - Illustration or photograph of cat or kitten
 - May be used on kittens from 8 weeks of age
 - Provides ongoing protection against fleas and the diseases they may transmit for one month
 - Picture of cat (or kitten)
 - Kills the vectors that may transmit Lyme disease, Rocky Mountain Spotted fever, babesiosis, ehrlichiosis, bartonellosis, cytauxzoonosis and heartworm disease
 - Kills fleas that may serve as an intermediate host for tapeworms (*Dipylidium caninum*)
 - Stops existing flea infestations by rapidly killing adult fleas
 - Prevents (re-)infestation for one month
2. Agency requirements with respect to the continued registration:
1. The registration for this product is time-limited and expires **two years from the date this product is released** for shipment bearing the revised language. You must provide the Agency with a projected release for shipment date within 30 days of the date of this letter. The Agency will calculate the expiration date based on the projected release date until an actual release date is provided in writing.
3. Reporting of incident data for this product:
1. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on October 1, 2010. The quarterly reports are due two months after each quarter ends.
Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci)
The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot#
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred. (mm/dd/yyyy)
 - State in which the incident occurred. (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)

- Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
2. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
- All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular> oral> dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label (if applicable).
 - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range (if applicable).
 - Table showing number of incidents for each dog breed.
 - Table showing number of incidents in dogs for each clinical sign.
 - Table showing number of incidents in dogs for each organ system.
 - Report aggregate incidents, but do not combine moderate and minor incidents.
4. Other Comments:
1. This product has met the requirements for Child Resistant Packaging (CRP) except for those listed in 2(b) above, however, the Agency reserves the right to reevaluate the associated data if:
 1. an incident report shows any problems in human, and/or
 2. epidemiological evidence indicates a problem once the products reach the marketplace.
 2. Consider limiting the formulations of each product to one basic confidential statement of formula, if applicable. The Agency may require this in the future. It is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
 3. If the Agency determines that future mitigation measures are necessary for all pet spot-on products, you will be informed, and be expected to comply. If mitigation measures are necessary, the Agency may take appropriate regulatory actions.
5. You must submit two copies of the revised final printed labels and (Master label and Production Copies) for all sizes for the Agency records, before the product is released for shipment.

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If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Submit one copy of the revised final printed label for the record before the product is released for shipment.

A stamped copy of the label is enclosed for your records.



Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"

2382-185 D433462.DOCX

{Pending Master Label}

EFFIPRO[®] TOPICAL SOLUTION FOR CATS

FOR USE ONLY ON CATS AND KITTENS 8 WEEKS OLD OR OLDER

For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice
EFFIPRO[®] TOPICAL SOLUTION FOR CATS contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice on cats.

EFFIPRO[®] TOPICAL SOLUTION FOR CATS contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice on cats 8 weeks old or older.

ACTIVE INGREDIENT:

Fipronil..... 9.6%

OTHER INGREDIENTS:..... 90.4%

TOTAL:..... 100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION
READ ENTIRE LABEL BEFORE EACH USE**

**ACCEPTED
with COMMENTS
in EPA Letter Dated
JAN 14 2011
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2382-186**

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

HAZARDS TO HUMANS

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. Possible temporary irritation may occur at the site where EFFIPRO[®] TOPICAL SOLUTION FOR CATS was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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.
IF ON SKIN:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p>Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for health concerns, emergency medical treatment information or pesticide incidents.</p>	

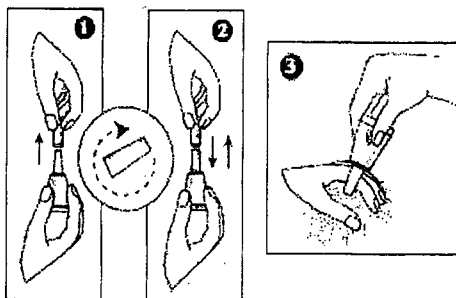
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any 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.

For killing fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks, (including those tick vectors which may transmit Lyme disease and other tick borne diseases), mosquitoes and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows:

APPLICATION DIRECTIONS (HOW TO APPLY)

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part pet's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
Deposit entire contents by squeezing the applicator at a single site on pet's skin.
Ensure that EFFIPRO® FOR CATS is not applied superficially on pet's hair.



EFFIPRO® TOPICAL SOLUTION FOR CATS is also approved for control of flea, tick, mosquito and chewing lice infestations in breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

EFFIPRO® TOPICAL SOLUTION FOR CATS will kill fleas, ticks and chewing lice completely when applied monthly.

Fleas: EFFIPRO® FOR CATS can control fleas for up to six weeks. However, a monthly application is recommended if your pet has fleas that may cause flea allergy dermatitis, or if reinfestation is likely.

Ticks: EFFIPRO® FOR CATS can kill ticks for a month or longer. However, where tick control is consistently needed, monthly applications are recommended.

Mosquitoes: When applied monthly, EFFIPRO® FOR CATS can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® FOR CATS. Avoid contact with treated area until dry.

EFFIPRO® FOR CATS is effective after bathing, shampooing, water immersion, or sunlight exposure.

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 /CONTAINER DISPOSAL: If empty: Nonrefillable. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risk of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

Net Contents 1 or 36 single-dose applicators per package. Each applicator contains 0.5 mL of solution.

EPA Reg. No. 2382-XXX

EPA Est. No. 2382-FRA-1

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH TX 76161
1-800-338-3659

Made in France
EFFIPRO® is a registered trademark of Virbac.
Questions or comments?
Call: 1-800-338-3659

EFFIPRO[®] TOPICAL SOLUTION FOR CATS

FOR USE ON CATS AND KITTENS 8 WEEKS OLD OR OLDER

For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice

- Easy and convenient application (applications)
- ~~Stops existing infestations and prevents establishment of new infestations~~
- ~~Pest reinfestations prevented for a month or longer~~
- Waterproof (remains effective after bathing and swimming)
- Kills emerged young-adult fleas prior to egg-laying
- ~~Kills fleas that may transmit disease, including bartonellosis, tapeworm and tularemia~~
- Kill fleas that may cause flea allergy dermatitis (FAD) or anemia
- ~~Kills all species of gnats and ticks, including dog ticks, lone star ticks, and deer ticks (ticks that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, anaplasmosis, cytauxzoonosis, and other tick-borne diseases)~~
- Kills mosquitoes
- Chewing lice infestations are rapidly eliminated
- Can be used on breeding, pregnant and lactating queens

EFFIPRO[®] TOPICAL SOLUTION FOR CATS contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice.

Open resealable label for directions & precautions

(Detachable) calendar (monthly application) reminder stickers with illustration of cat or kitten.

See back panel for additional precautionary statements.

See enclosed inserts for directions for use.

See package insert for frequency of application.

Lot No.:

Detachable calendar reminder stickers (with illustration of cat or kitten).

ADDITIONAL MARKETING TEXT

- Protects cats and kittens over 8 weeks of age from fleas for at least one month
- ~~Buy in the quantity of 12. Money back guarantee. (your money back) (your money back) (your money back)~~
- ~~Quick-acting, easy to apply~~
- Prevents (re-)infestation (of fleas) for at least one month
- Monthly treatment is recommended for optimal control and prevention of fleas
- Begins working upon application
- Once monthly application
- Easy to apply spot-on (topical) application
- Convenient, easy to apply
- ~~Fluorinated ether free~~
- ~~No noticeable odors~~
- Convenient to use
- Convenient to use (easy to apply) topical treatment
- Still works after exposure to sunlight
- Convenient topical treatment
- ~~Removal of fleas is important in the prevention of disease transmission by these parasites~~
- ~~Approved and licensed veterinarians~~
- ~~Sold by veterinarians~~
- Effective monthly control of adult fleas
- Kills fleas that may transmit disease, including bartonellosis
- Kills fleas
- Easy to apply, effective control of fleas that lasts at least 1 month
- ~~Regular use breaks the flea life cycle~~
- Proven treatment technology for flea infestations
- For cats and kittens 8 weeks of age or older
- Effective monthly treatment against fleas
- Protects (your cat and kitten 8 weeks of age or older) from fleas for one month
- Protects from fleas for one month
- Easy, spot on (topical) application
- ~~Partner or parentless of you: money back (please call our professional staff at xxx-xxx-xxxx if you have any questions or comments about EFFIPRO[®] TOPICAL SOLUTION FOR CATS)~~

{Product Claims to be printed on package insert or booklet outsert}



EFFIPRO[®] TOPICAL SOLUTION FOR CATS

FOR USE ON CATS AND KITTENS 8 WEEKS OLD OR OLDER

For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice

- Easy and convenient application (applications)
- Stops existing infestations and prevents establishment of new infestations
- ~~Fast reinfestations are rare, for a month or longer~~
- Waterproof (remains effective after bathing and swimming)
- Kills emerged young-adult fleas prior to egg-laying
- ~~Kills fleas that may transmit disease including bartonellosis, tapeworm and tularemia~~
- ~~Kill fleas that may cause flea allergy dermatitis (FAD) or anemia~~
- ~~Kills all species of ear and eye mites, American dog ticks, lone star ticks and deer ticks (ticks that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, anaplasmosis, and other tick-borne diseases)~~
- Kills mosquitoes
- Chewing lice infestations are rapidly eliminated
- Can be used on breeding, pregnant and lactating queens

EFFIPRO[®] TOPICAL SOLUTION FOR CATS contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice.

EFFIPRO[®] TOPICAL SOLUTION FOR CATS contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice on cats 8 weeks old or older.

ACTIVE INGREDIENT:

Fipronil 9.6%

OTHER INGREDIENTS: 90.4%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

HAZARDS TO HUMANS

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. Possible temporary irritation may occur at the site where EFFIPRO[®] TOPICAL SOLUTION FOR CATS was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals.

PHYSICAL OR CHEMICAL HAZARDS

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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.
IF ON SKIN:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p>Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for health concerns, emergency medical treatment information or pesticide incidents.</p>	

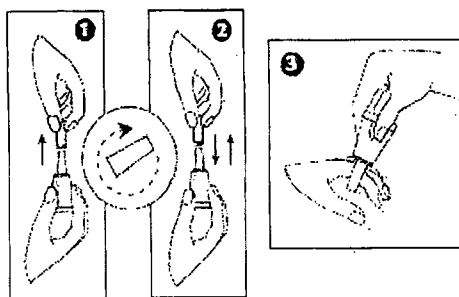
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any 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.

For killing fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks, (including those tick vectors which may transmit Lyme disease and other tick borne diseases), mosquitoes and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows:

APPLICATION DIRECTIONS (HOW TO APPLY)

1. Remove one applicator from packaging. Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip. Push cap down to break seal. Remove cap prior to treatment application.
3. Part pet's hair between shoulder blades until skin is visible. Place applicator tip directly against exposed skin. Deposit entire contents by squeezing the applicator at a single site on pet's skin. Ensure that EFFIPRO® FOR CATS is not applied superficially on pet's hair.



EFFIPRO® TOPICAL SOLUTION FOR CATS is also approved for control of flea, tick, mosquito and chewing lice infestations in breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

EFFIPRO® TOPICAL SOLUTION FOR CATS will kill fleas, ticks and chewing lice completely when applied monthly.

Fleas: EFFIPRO® FOR CATS can control fleas for up to six weeks. However, a monthly application is recommended if your pet has fleas that may cause flea allergy dermatitis, or if reinfestation is likely.

Ticks: EFFIPRO® FOR CATS can kill ticks for a month or longer. However, where tick control is consistently needed, monthly applications are recommended.

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Mosquitoes: When applied monthly, EFFIPRO® FOR CATS can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® FOR CATS. Avoid contact with treated area until dry.

EFFIPRO® FOR CATS is effective after bathing, shampooing, water immersion, or sunlight exposure.

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 /CONTAINER DISPOSAL: Nonrefillable. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available. **If partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risk of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

Net Contents 1 or 36 single-dose applicators per package. Each applicator contains 0.5 mL of solution.

Open resealable label for directions & precautions

(Detachable) calendar (monthly application) reminder stickers (with illustration of cat or kitten).

EPA Reg. No. 2382-XXX
EPA Est. No. 2382-FRA-1

VIRBAC AH, INC.
PO BOX 162059
FORT WORTH TX 76161
1-800-338-3659

Made in France
EFFIPRO® is a registered trademark of Virbac.

{Product Claims to be printed on outer package or other places}

EFFIPRO® TOPICAL SOLUTION FOR CATS

For cats and kittens 8 weeks or older

For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice

- Easy and convenient application (applications)
- Stops existing infestations and prevents establishment of new infestations
- ~~Best infestations prevented for 2 months or longer~~
- Waterproof (remains effective after bathing and swimming)
- Kills emerged young-adult fleas prior to egg-laying
- ~~Kills fleas that may transmit disease including bartonellosis, tapeworm and tularemia~~
- Kill fleas that may cause flea allergy dermatitis (FAD) or anemia
- ~~Kills all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (ticks that may transmit Lyme disease, Borrelia burgdorferi, spotted fever, babesiosis, ehrlichiosis, anaplasmosis, cytauxzoonosis, and other tick borne diseases)~~
- Kills mosquitoes
- ~~Chewing lice infestations are rapidly eliminated~~
- Can be used on breeding, pregnant and lactating queens

EFFIPRO® TOPICAL SOLUTION FOR CATS contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice.

Questions or comments?
Call: 1-800-338-3659

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{Text for Front Panel of Outer Package (box)}



EFFIPRO[®] TOPICAL SOLUTION FOR CATS

Kills fleas, ticks, mosquitoes and chewing lice

- For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice
- Waterproof

**For Cats and Kittens
8 weeks old and older**

ACTIVE INGREDIENT:

Fipronil..... 9.6%

OTHER INGREDIENTS: 90.4%

TOTAL: 100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See back panel for additional precautionary statements.

See enclosed inserts for directions for use.

Illustration or photograph of cat or kitten

Lift here to open

(1 or 36) applicators 0.5 ml

For animal use only

Batch No.

{Text for Front Panel of Outer Package (box)} after opening

EFFIPRO[®] TOPICAL SOLUTION FOR CATS

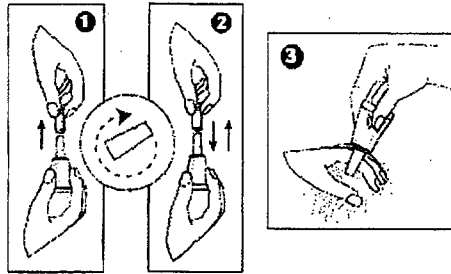
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any 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.

For killing fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks, (including those tick vectors which may transmit Lyme disease and other tick borne diseases), mosquitoes and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows:

APPLICATION DIRECTIONS [HOW TO APPLY(?)]

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
2. Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
3. Part pet's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
Deposit entire contents by squeezing the applicator at a single site on pet's skin.
Ensure that EFFIPRO[®] FOR CATS is not applied superficially on pet's hair.



LIMITED WARRANTY AND DISCLAIMER

To the extent consistent with applicable law, buyer assumes all risks of use, storage, or handling of this product not in accordance with directions. Buyer and user assume all risk of use and handling of this material when such use and handling are contrary to label instructions. To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

{Text for Back Panel of Outer Package (box)}



EFFIPRO[®] TOPICAL SOLUTION FOR CATS

FOR USE ONLY ON CATS AND KITTENS 8 WEEKS OLD OR OLDER

For convenient, quick-acting, long-lasting, effective control of fleas, ticks, mosquitoes and chewing lice for CATS and KITTENS 8 weeks or older.

EFFIPRO[®] TOPICAL SOLUTION FOR CATS contains the active ingredient fipronil, which controls infestations caused by fleas, ticks, mosquitoes and chewing lice on cats 8 weeks old or older.

ACTIVE INGREDIENT:

Fipronil..... 9.6%

OTHER INGREDIENTS: 90.4%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

HAZARDS TO HUMANS

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. Possible temporary irritation may occur at the site where EFFIPRO® TOPICAL SOLUTION FOR CATS was applied. Contact a veterinarian immediately if signs become persistent or become more severe during the first few days following application. If an unusual reaction is observed following initial application, a veterinarian should be consulted before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals.



FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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.
IF ON SKIN:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p>Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for health concerns, emergency medical treatment information or pesticide incidents.</p>	

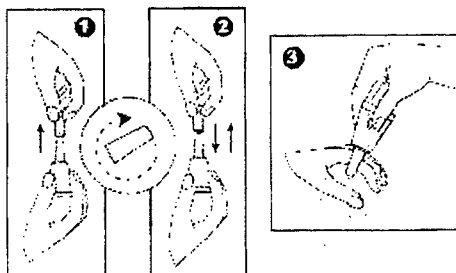
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any 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.

For killing fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks, (including those tick vectors which may transmit Lyme disease and other tick borne diseases), mosquitoes and chewing lice; apply to CATS or KITTENS (8 weeks old or older) as follows:

APPLICATION DIRECTIONS

1. Remove one applicator from packaging.
Hold applicator upright and remove cap.
Invert cap and place other end back onto applicator tip.
Push cap down to break seal.
Remove cap prior to treatment application.
2. Part pet's hair between shoulder blades until skin is visible.
Place applicator tip directly against exposed skin.
Deposit entire contents by squeezing the applicator at a single site on pet's skin.
Ensure that EFFIPRO® FOR CATS is not applied superficially on pet's hair.



EFFIPRO® TOPICAL SOLUTION FOR CATS is also approved for control of flea, tick, mosquito and chewing lice infestations in breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

EFFIPRO® TOPICAL SOLUTION FOR CATS will kill fleas, ticks and chewing lice completely when applied monthly.

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Fleas: EFFIPRO® FOR CATS can control fleas for up to six weeks. However, ~~a monthly application is recommended~~ if your pet has fleas that may cause flea allergy dermatitis, or if reinfestation is likely.

Ticks: EFFIPRO® FOR CATS can kill ticks for a month or longer. However, where tick control is consistently needed, ~~monthly applications are recommended.~~

Mosquitoes: When applied monthly, EFFIPRO® FOR CATS can kill mosquitoes within 24 hours (for up to 14 days), and within 48 hours (for up to 28 days).

Notes: Wait at least 30 days before re-application of EFFIPRO® FOR CATS. Avoid contact with treated area until dry.

EFFIPRO® FOR CATS is effective after bathing, shampooing, water immersion, or sunlight exposure.

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 /CONTAINER DISPOSAL: Nonrefillable. Do not reuse or refill this container. If empty: Place in trash or offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

See package insert for frequency of application.

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EPA Reg. No. 2382-XXX
EPA Est. No. 2382-FRA-1

{Text for Left Side Panel of Outer Package (box)}



EFFIPRO® TOPICAL SOLUTION FOR CATS (1 or 36) applicators
~~For cats and kittens~~
~~8 weeks old or older~~
(1 or 36) applicators 0.5 ml

~~Illustration or photograph of cat or kitten~~

Lot No.:

{Text for Right Side Panel of Outer Package (box)}



EFFIPRO® TOPICAL SOLUTION FOR CATS (1 or 36) applicators
~~For cats and kittens~~
~~8 weeks old or older~~
(1 or 36) applicators 0.5 ml

~~Illustration or photograph of cat or kitten~~

Lot No.:

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20

{Text for Top Panel of Outer Package (box)}



EFFIPRO® TOPICAL SOLUTION FOR CATS (1 or 36) applicators
~~For cats and kittens~~
~~8 weeks old or older~~
(1 or 36) applicators 0.5 ml

~~Illustration or photograph of cat or kitten~~

Lot No.:

{Text for Bottom Panel of Outer Package (box)}



EFFIPRO® TOPICAL SOLUTION FOR CATS (1 or 36) applicators
~~For cats and kittens~~
~~8 weeks old or older~~
(1 or 36) applicators 0.5 ml

~~Illustration or photograph of cat or kitten~~

Lot No.:

{Text for Foil of Blister package}

Virbac
EFFIPRO® Topical Solution
Only for use on cats
0.5 mL
Contains fipronil (9.6%)
Keep out of reach of children
See full label for additional directions
CAUTION
EPA Reg. No.

{Text for Applicator Tube}

Virbac
EFFIPRO®
Topical Solution
Only for use on cats
0.5 mL
Contains fipronil (9.6%)
Keep out of reach of children
See full label for additional directions
CAUTION
EPA Reg. No.
Lot No.:

{Additional Marketing Text for Placement on Outer Package, Package Insert or Booklet Outsert}

- Protects cats and kittens over 8 weeks of age from fleas for at least one month
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- Prevents (re-)infestation (of fleas) for at least one month
- Monthly treatment is recommended for optimal control and prevention of fleas
- Begins working upon application
- Once monthly application
- Easy to apply spot-on (topical) application
- Convenient, easy to apply
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- Convenient to use
- Convenient to use (easy to apply) topical treatment
- Still works after exposure to sunlight
- Convenient topical treatment
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- Effective monthly control of adult fleas
- Kills fleas that may transmit disease, including bartonellosis
- Kills fleas
- Easy to apply, effective control of fleas that lasts at least 1 month
- Regular use breaks the flea life cycle
- Proven treatment technology for flea infestations
- For cats and kittens 8 weeks of age or older
- Effective monthly treatment against fleas
- Protects (your cat and kitten 8 weeks of age or older) from fleas for one month
- Protects from fleas for one month
- Easy, spot on (topical) application
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- Kills fleas that may cause flea allergy dermatitis (FAD) and anemia
- ~~Kills fleas that may cause flea allergy dermatitis (FAD) and anemia~~
- Kills adult fleas for one month
- Convenient topical treatment for cats
- ~~Persistent efficacy through 30 days~~
- Prevents (re-)infestation for one month
- Monthly treatment (all year) is recommended for control and prevention of fleas
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- Quick drying, non-greasy
- Convenient to use (easy to apply)
- ~~Available for purchase at your veterinarian~~
- ~~Kills fleas that may transmit disease, including bartonellosis, tapeworm and tularemia~~
- Easy to apply, effective control of fleas that lasts 1 month
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- Regular (monthly) use breaks the flea life cycle
- Treatment of cats with EFFIPRO® TOPICAL SOLUTION FOR CATS kills fleas that may cause flea allergy dermatitis (FAD)
- ~~May be used on kittens from 8 weeks of age~~
- Proven treatment technology for flea infestation
- ~~Easy to use applicator makes treatment simple (trouble free, smooth) and comfortable for your pet~~
- EFFIPRO® TOPICAL SOLUTION FOR CATS kills fleas on your cat
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- ~~Protects against protection against fleas and the diseases they may transmit for one month~~
- Kills fleas which may cause anemia
- Fleas do not have to bite to die
- Kills fleas that may cause anemia
- Protects your cat from flea infestation that may cause anemia
- Remains effective after exposure to sunlight
- Proven treatment (technology) for flea infestation
- Protects for one month
- Effective monthly treatment of fleas, ticks, and mosquitoes
- Kills fleas, ticks and mosquitoes for one month
- ~~Protects cats and kittens over 8 weeks of age from fleas for at least one month~~
- Remains effective after bathing

