


2382-188

7/6/2012

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 <p style="text-align: center;"><b>ENVIRONMENTAL PROTECTION AGENCY</b></p> <p style="text-align: center;">Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave N W Washington D C 20460</p>	<p>EPA Registration No</p> <p style="text-align: center;">2382 188</p>	<p>Date of Issuance</p> <p style="text-align: center;">July 6 2012</p>
<p style="text-align: center;"><b>NOTICE OF PESTICIDE</b></p> <p style="text-align: center;"><input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration</p> <p style="text-align: center;">(under the Federal Insecticide Fungicide and Rodenticide Act as amended)</p>	<p>Term of Issuance</p> <p style="text-align: center;"><b>Unconditional</b></p> <hr/> <p>Name of Pesticide Product</p> <p style="text-align: center;"><b>EFFIPRO® PLUS TOPICAL SOLUTION FOR CATS</b></p>	
<p><b>Name and Address of Registrant (include ZIP Code)</b></p> <p>Virbac Animal Health Inc P O Box 162059 Fort Worth TX 76161</p> <p><b>Note</b> 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</p>		
<p>On the basis of information furnished by the registrant the above named pesticide is hereby registered under the Federal Insecticide Fungicide and Rodenticide Act</p> <p>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</p> <p>This action is taken under the authority of section 3(c)(5) of the Federal Insecticide Fungicide and Rodenticide Act as amended Registration under this section does not eliminate the need for continual reassessment of pesticides EPA may require submission of data at any time to maintain the registration of your product</p> <p style="text-align: center;"><b>Terms of Registration</b></p> <p>1 EPA has registered the product listed above provided that the following change is made to the label before you release the product for shipment Revise the EPA Registration Number to read EPA Registration No 2382 188</p> <p>2 The Net Contents must be displayed in accordance with the description identified in the Labeling Consistency Committee s clarification This information may be located at the following Agency web site under miscellaneous <a href="http://www.epa.gov/opp00001/regulating/labels/label_review_faqs.htm#miscellaneous">http://www.epa.gov/opp00001/regulating/labels/label_review_faqs.htm#miscellaneous</a> Regarding listing net contents Net weight or contents must be stated on a pesticide label in accordance with FIFRA (2)(q)(2)(C)(iii) and 40 CFR 156.10(a)(1)(iii) EPA interpretation of the statutory and regulatory requirements is that the label must state the total weight for the entire contents as sold and distributed In</p>		
<p>Signature of Approving Official</p> <p style="text-align: center;">Refer to Page 3</p> <p>Richard J Gebken Product Manager (10) Registration Division Insecticide Branch</p>	<p>Date</p> <p style="text-align: center;">July 6 2012</p>	

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addition the label may indicate the net weight and quantity of individual units within the carton For example Net Weight 6.25 lbs (20 5oz packets) For additional information regarding the Net Weight/Contents statement please reference Chapter 17 of the Label Review Manual at [http://www.epa.gov/oppfead1/labeling/lrm/chap\\_17.htm](http://www.epa.gov/oppfead1/labeling/lrm/chap_17.htm)

3 This registration is time limited and expires two years from the date this product is first released for shipment You must provide the Agency with a projected release for shipment date in writing within 30 days of the date of this Notice of Registration The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing

4 Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e. no alternate formulations or minor formulation amendments will be submitted and/or approved for this product except to allow for alternate sources of any individual inert ingredient)

5 You must submit the following data within the timeframe described below Within sixteen (16) months of the date on this Notice of Registration provide to the Agency acceptable data packages for Guideline Studies OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability)

6 You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1, 2012. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) 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

7 Along with the enhanced incident reporting, you must submit an analysis of all incidents seen to include the following details:

- a All minor dermal and ocular irritation reports
- b 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.
- c A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure
- d Summary table for dogs and table for cats showing number of incidents that are believed due to

secondary exposure (e.g. multi pet households)

e 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

f A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label

g 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

h Table showing number of incidents for each dog breed

i Table showing number of incidents in dogs for each clinical sign

j Table showing number of incidents in dogs for each organ system

k Report aggregate incidents but do not combine moderate and minor incidents

8 If EPA determines that future mitigation measures are necessary for all pet spot on products the Agency will inform all registrants concerned If mitigation measures are necessary EPA may take regulatory action

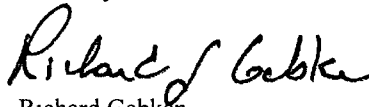
9 Virbac Inc should adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot On Mitigation Plan* available at the following internet site [http://www.epa.gov/pesticides/health/spot\\_on\\_meetings.html](http://www.epa.gov/pesticides/health/spot_on_meetings.html)

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data and submit acceptable responses required for registration review of your product under FIFRA

Two copies of the finished labeling must be submitted prior to releasing the product for shipment If you fail to comply with all of the **Terms of Registration** stated above the registration will be subject to cancellation in accordance with FIFRA sec 6(e) and/or automatically expire Your release for shipment of the product constitutes your acceptance of these conditions

A copy of your label stamped "Accepted with Comments" is enclosed for your records If you have any questions concerning this action please contact me Richard J Gebken at (703) 305 6701 or gebken richard@epa.gov

Sincerely



Richard Gebken  
Product Manager 10  
Insecticide Branch  
Registration Division (7505C)

Enclosure

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**{Master Label}**  
**Virbac's Master Label**  
 Date December 13 2011      Version US 7      EPA Reg No 2382 XXX  
 Fipronil + Pyriproxyfen Topical Solution for Cats

*Virbac*

**EFFIPRO<sup>®</sup> PLUS TOPICAL SOLUTION FOR CATS**

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

**ACTIVE INGREDIENTS**

Fipronil 95/  
 Pyriproxyfen 11.5/

**OTHER INGREDIENTS**

79.0/

**TOTAL**

100.0/

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

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated**

July 6 2012

*Under the Federal Insecticide Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg No 2382 188*

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**HAZARDS TO HUMANS**

Harmful if swallowed or absorbed through the skin Causes moderate eye irritation Avoid contact with skin eyes or clothing Wash hands thoroughly with soap and water after handling and before eating drinking chewing gum using tobacco or using the toilet

**HAZARDS TO DOMESTIC ANIMALS**

**For external use only** Do not use on kittens under 8 weeks of age Sensitivities may occur after using ANY pesticide product for pets If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water If signs continue consult a veterinarian immediately Possible temporary irritation may occur at the site where EFFIPRO PLUS 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 application Certain medications can interact with pesticides

	<b>FIRST AID</b>
<b>IF SWALLOWED</b>	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
<b>IF IN EYES</b>	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
<b>IF ON SKIN OR CLOTHING</b>	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
<b>Have product container or label with you when calling a poison control center or doctor or going for treatment</b> <b>You may also contact the Hotline number 1 800 338 3659 for human and veterinary health concerns emergency medical treatment information or pesticide incidents</b>	

**DIRECTIONS FOR USE**

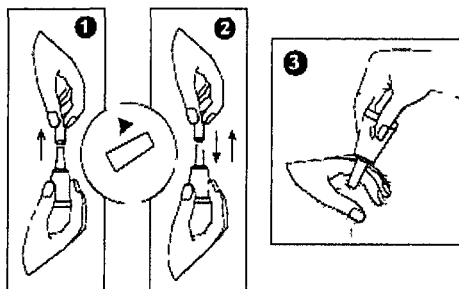
It is a violation of Federal law to use this product in any manner inconsistent with its labeling Do not allow children to apply product **TO PREVENT HARM TO YOU AND YOUR CAT READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE**

FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY USE ON CATS ONLY DO NOT USE ON DOGS PUPPIES OR RABBITS DO NOT USE ON OTHER ANIMALS

For killing fleas flea eggs flea larvae all stages of **Brown dog ticks American dog ticks Lone Star ticks and Deer ticks** (that [which] may transmit [carry] Lyme disease) 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
- 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 cat 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 cat s skin  
Ensure that EFFIPRO PLUS Topical Solution for Cats is not applied superficially on cat s hair



**FREQUENCY OF APPLICATION**

EFFIPRO® PLUS Topical Solution for Cats will kill fleas ticks and chewing lice when applied monthly

**Fleas** EFFIPRO PLUS Topical Solution for Cats can control fleas for up to six weeks Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis (FAD) or if reinfestation is likely EFFIPRO® PLUS Topical Solution for Cats can control flea eggs (and larvae) for up to three months (90 days)

**Ticks** EFFIPRO® PLUS Topical Solution for Cats can kill ticks for a month or longer Apply monthly where tick control is consistently needed

**Chewing Lice** EFFIPRO® PLUS can kill chewing lice for a month or longer Apply monthly where chewing lice control is consistently needed

**Mosquitoes** When applied monthly EFFIPRO® PLUS Topical Solution 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 PLUS Topical Solution for Cats Avoid contact with treated area until dry

**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 container 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 risks 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 3 6 or 36 single dose applicator(s) per package Each applicator contains 0 017 fl oz (0 5 mL) of solution

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

EPA Reg No 2382 XXX

EPA Est No 2382 XXX

VIRBAC AH INC  
PO BOX 162059

FORT WORTH TX 76161  
1 800 338 3659

Made in France  
EFFIPRO® is a registered trademark of Virbac S A in the United States  
Questions or comments?  
Call 1 800 338 3659

**{Text for Front Panel, Back Panel and Side Panel}**

See package insert(s) for directions for use and frequency of application  
Open resealable label for directions for use  
Open resealable label for directions for use and storage and disposal  
See back panel for additional precautionary statements  
See package insert(s) for frequency of application  
See enclosed insert(s) for directions for use and storage and disposal  
See enclosed insert(s) for directions for use

Use only on cats  
For Use on Cats only  
Only for cats and kittens 8 weeks old or older  
(1 3 6 or 36) applicator(s) 0 017 fl oz (0 5 ml)

Photograph of cat or kitten

Lift here to open (LIFT HERE TO OPEN)

**{Text for Foil of Blister package}**

**Virbac**  
EFFIPRO® PLUS Topical Solution for Cats  
Only for use on cats / 0 017 fl oz (0 5 ml)  
Contains fipronil (9 5 / ) and pyriproxyfen (11 5 / )  
KEEP OUT OF REACH OF CHILDREN  
CAUTION  
See full label for additional directions  
EPA Reg No 2382 XXX

**{Text for Applicator Tube}**

**Virbac**  
EFFIPRO PLUS  
Topical Solution for Cats  
Only for use on cats  
0 017 fl oz (0 5 mL)  
Contains fipronil (9 5 / ) and pyriproxyfen (11 5 / )  
KEEP OUT OF REACH  
OF CHILDREN  
CAUTION  
See full label for additional directions  
EPA Reg No 2382 XXX

**MARKETING CLAIMS**

**[Multiple infestations]**

For convenient quick acting long lasting effective control of fleas flea eggs flea larvae ticks mosquitoes and chewing lice (for 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 old or older)  
EFFIPRO® PLUS 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)  
EFFIPRO® PLUS Topical Solution for Cats contains the active ingredient pyriproxyfen which controls reinfestation caused by flea eggs flea larvae (on cats) (8 weeks old or older)  
For killing fleas all stages of Brown dog ticks American dog ticks Lone Star ticks and Deer ticks (which/that may carry (transmit) Lyme disease) mosquitoes and chewing lice apply to CATS or KITTENS (8 weeks old or older) as follows (followed by application directions)  
Persistent flea and tick efficacy for up to one month (4 weeks) (30 days)

Prevents flea and tick (re)infestation for up to one month (4 weeks)  
 Effective monthly application for (on) fleas and ticks  
 Effective monthly application for cats (and kittens) against fleas and ticks  
 Kills fleas and ticks for up to one month (4 weeks)  
 Kills fleas ticks mosquitoes and chewing lice  
 Kills fleas ticks mosquitoes and lice  
 Kills fleas flea eggs flea larvae ticks mosquitoes and chewing lice  
 Kills fleas flea eggs flea larvae ticks mosquitoes and lice  
 Apply monthly for control and prevention of fleas and ticks  
 Protects against fleas and ticks for up to one month  
 EFFIPRO® PLUS Topical Solution for Cats will kill fleas ticks and chewing lice when applied monthly  
**Fleas** EFFIPRO PLUS Topical Solution for Cats can control fleas flea eggs and flea larvae for up to (six weeks)  
 Apply monthly if your cat has fleas that may cause Flea Allergy Dermatitis or if reinfestation is likely  
**Ticks** EFFIPRO PLUS Topical Solution for Cats can kill ticks for a month or longer Apply monthly where tick control is consistently needed  
**Mosquitoes** When applied monthly EFFIPRO® PLUS Topical Solution 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 PLUS Topical Solution for Cats Avoid contact with treated area until dry

[Fleas]

Kills newly emerged adult fleas prior to egg laying  
 Kills fleas that may transmit bartonellosis  
 Kills fleas that may transmit bartonellosis tularemia and tapeworm  
 Kills fleas that may transmit (bartonellosis) (tularemia) (and) (tapeworm)  
 Kills fleas that may transmit (bartonellosis) (tularemia) (and) (tapeworm infestations)  
 Kills fleas that may transmit bartonellosis and tularemia  
 Kills fleas flea eggs and flea larvae  
 Prevents development of all flea stages (flea eggs flea pupae and flea larvae) for up to (3 months) (90 days)  
 Kills flea eggs for up to (3 months) (90 days)  
 Sterilizes and kills fleas  
 Sterilizes fleas for up to (3 months) (90 days)  
 Prevents all flea stages (adult fleas flea eggs flea pupae and flea larvae)  
 Prevents development of all flea stages (flea eggs flea pupae and flea larvae) for up to (3 months) (90 days)  
 With pyriproxyfen (IGR) to break flea life cycle  
 insect growth regulator  
 Dual Action(!) fipronil and pyriproxyfen (IGR) effectively breaks the flea life cycle  
 Kill fleas that may cause Flea Allergy Dermatitis (FAD) or flea bite anemia  
 Effective monthly control of adult fleas  
 Kills fleas  
 Easy to apply control of (for) fleas that lasts for up to 1 month (4 weeks)  
 Protects (your cat and kitten 8 weeks of age or older) from fleas for up to one month (4 weeks)  
 Protects from fleas for up to one month (4 weeks)  
 Kills adult fleas for up to one month (4 weeks)  
 Apply monthly (all year) for control and prevention of fleas  
 Regular (monthly) use breaks the flea life cycle  
 EFFIPRO PLUS Topical Solution for Cats (rapidly) kills fleas that may cause Flea Allergy Dermatitis (FAD)  
 EFFIPRO® PLUS Topical Solution for Cats kills fleas on your cat  
 Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)  
 Kills fleas which/that may cause flea bite anemia  
 Fleas do not have to bite to die  
 Protects your cat from flea infestation that may cause flea bite anemia  
 The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)  
 Protects cats and kittens over 8 weeks of age from fleas for up to one month (4 weeks)  
 Prevents flea (re)infestation for up to one month (4 weeks)  
 Prevents flea eggs from hatching or developing into larvae or adult stages (for up to 90 days (3 months))

[Ticks]

Kills all stages of Brown dog ticks American dog ticks Lone Star ticks and Deer ticks (including those which [that] may transmit [carry] Lyme disease Rocky Mountain Spotted Fever babesiosis ehrlichiosis anaplasmosis and cytauxzoonosis)  
 Kills ticks including those that may transmit Lyme disease  
 Kills ticks including Deer ticks (which may transmit Lyme disease) American dog ticks (which may transmit Rocky Mountain Spotted Fever) Brown dog ticks (which may transmit ehrlichiosis) and Lone Star ticks (which may transmit hepatzoonosis) for up to one month (4 weeks)  
 Kills ticks including Deer ticks (which may transmit Lyme disease) American dog ticks (which may transmit Rocky Mountain Spotted Fever) and Brown dog ticks (which may transmit ehrlichiosis) for up to one month (4 weeks)  
 Kills Brown dog ticks (*Rhipicephalus* spp) American dog ticks (*Dermacentor variabilis*) Deer ticks (*Ixodes* spp) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks)  
 Kills Lone Star ticks (*Amblyomma americanum*) for up to 4 weeks (for up to one month)

Protects Cats and kittens from ticks for up to one month

**[Mosquitoes]**

Kills mosquitoes  
Kills mosquitoes for up to 28 days

**[All others]**

Chewing lice infestations are rapidly eliminated  
May be used only on kittens from 8 weeks of age  
Begins working upon application  
Once monthly application  
Single application lasts up to 4 weeks (one month)  
Easy and convenient application (applications)  
Easy to apply spot on (topical) application  
Convenient easy to apply  
Convenient to use (easy to apply)  
Convenient to use (easy to apply) topical application  
Convenient topical application (for cats)  
Easy spot on (topical) application  
Quick drying non greasy  
Available from licensed veterinarians  
1 (3 6 36) applicator(s) (tube[s]) of 0 017 fl oz (0 5 mL)  
1 (3 6 36) applicator(s) (tube[s]) 0 017 fl oz (0 5 mL)  
1 (3 6 36) month(ly) dose(s) (application[s])  
1 applicator (tube) 1 month(ly) dose  
3 applicators (tubes) 3 (monthly) doses  
6 applicators (tubes) 6 (monthly) doses  
36 applicators (tubes) 36 (monthly) doses  
1 applicator containing 0 017 fl oz (0 5 mL)  
3 (6 36) applicators each containing 0 017 fl oz (0 5 mL)  
Remains effective after exposure to sunlight  
Remains effective after bathing  
Remains effective even after bathing water immersion or exposure to rain or sunlight  
Remains effective even after bathing  
Remains effective after exposure to rain and sunlight  
Still works after bathing or exposure to sunlight  
EFFIPRO PLUS Topical Solution for Cats is effective after bathing shampooing water immersion or sunlight exposure  
Still works after exposure to sunlight  
Waterproof (remains effective after bathing and swimming)