

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 23, 2019

Ann Tillman Agent, Pyxis Regulatory Consulting, Inc. TEVRA Brands, LLC 9100 F Street, Suite 200 Omaha, NE 68127

Subject: Label Amendment – Revising CRP fill volume for Option 1 small bulb, single applicator to include the 0.027 fl oz (0.8 ml) fill volume & revised labeling to adjust optional text with 4 ABN; and another ABN from a subsequent amendment
Product Name: TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats EPA Registration Number: 92413-10
Application Date: October 1, 2018, January 28, 2019
Decision Number: 544833, 548258

Dear Ms. Tillman:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Note: Proposed revisions to the CSF were not acceptable, in part due to CRP Option 4 not being supported in this amendment, and therefore the amended list of repacking facilities should be updated, accordingly. Also, a single basic formulation is permitted for spot-on products. The nominal concentrations for some of the proposed alternative sources of technicals were outside of the accepted, established range for the Basic CSF on file. Please note that the record for this product currently contains the following CSF:

• Basic CSF dated May 15, 2018

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide

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Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Dee Colby by phone at 703-347-8657, or via email at Colby.deanna@epa.gov.

Sincerely,

Venus Eagle, Product Manager 01 Invertebrate and Vertebrate Branch 3 Registration Division (7505P) Office of Pesticide Programs

Enclosure: Stamped Label

ACCEPTED 05/23/2019 Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

92413-10

#### **TEVRA Master Label**

Cats Spot On Imidacloprid + Pyriproxyfen

#### **{FRONT PANEL OF CARTON}**

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text]

{ } Braces indicate location of text on container or note to the EPA reviewer.

#### {Primary Brand Name} TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats {Alternate Brand Names: Tevrapet PROACT for Cats {see end of label for additional alternate brand names}

{Market Label-the word Cat will be at least 75% in height of the largest letter in the primary brand name.}

{Market Label-a large clear picture of a cat in the respective weight range will be on the front panel of the label.}

{One of the following statements will appear on appropriate weight band market label prominently on front panel, enclosed in a box, as required per Agency's pet spot-on mitigation measures}

For use ONLY on cats &[and] kittens [weighing] 2-[to ]5 lbs. and over 8 weeks old[of age][or older] {0.23 ml size package}{OR}

For use ONLY on cats &[and] kittens [weighing] 5-[to ]9 lbs. and over 8 weeks old[of age][or older] {0.40 ml size package}{OR}

For use ONLY on cats &[and] kittens [weighing] more than[over][>] 9 lbs. and over 8 weeks old[of age][or older] {0.80 ml size package}

{following text will be in addition to the above required language}
Small Cats {only for use on label for 2-5 lbs and 8 weeks or older product}{OR}
Medium Cats {only for use on label for 5-9 lbs and 8 weeks or older product}{OR}
Large Cats {only for use on label for >9 lbs and 8 weeks or older product}

#### **ACTIVE INGREDIENTS:**

Imidacloprid	
Pyriproxyfen	0.46%
OTHER INGREDIENTS.	<u>90.44%</u>
TOTAL:	100.00%

# **KEEP OUT OF REACH OF CHILDREN**

# WARNING

{Note to reviewer: Font size of the KOOROC statement and Signal word will be in compliance with Label Review Manual Ch. 3.}

See back [or side]label [panel] and insert within carton for FIRST AID and PRECAUTIONARY STATEMENTS and insert for complete Directions for Use

#### NET CONTENT: Z fl oz Y – X fl oz applicators

[0.0078 fl oz (0.23 mL) applicators] [0.014 fl oz (0.4 mL) applicators] [0.027 fl oz (0.8 mL) [applicators]

Cats and kittens weighing	contents
2-5 lbs	1 tube = 0.0078 fl oz (0.23 ml)
	2 tubes = 0.0156 fl. oz. (0.46 mL)
	3 tubes = 0.0234 fl oz (0.69 mL)
	4 tubes – 0.0312 fl oz (0.92 mL)
	6 tubes = 0.0468 fl oz (1.38 mL)
	8 tubes = 0.0624 fl oz (1.84 mL)
5-9 lbs	1 tube = 0.014 fl oz (0.4 mL)
	2 tubes = 0.028 fl. oz. (0.8 mL)
	3 tubes = 0.042 fl oz (1.20 mL)
	4 tubes = 0.056 fl oz (1.6 mL)
	6 tubes = 0.084 fl oz (2.4 mL)
	8 tubes =0.112 fl oz (3.2 mL)
>9 lbs	1-tube = 0.027 fl. oz. (0.8 mL)
	2 tubes = 0.054 fl. oz. (1.6 mL)
	3 tubes = 0.081 fl oz (2.4 mL)
	4 tubes = 0.106 fl oz (3.2 mL)
	6 tubes = 0.162 fl oz (4.8 mL)
	8 tubes =0.216 fl oz (6.4 mL)

**NET CONTENTS:** Each carton contains 1[2][3][4][6][8] applicators.

#### **{Note to reviewer:**

OPTION 1 for clear CRP applicators in singles or strips of 3 or 4: X is the liquid amount of one applicator; Y is the number of applicators that are in the carton; Z is the sum of the liquid amounts; Y can be 1, 2, 3, 4, 6, and 8 for the 0.0078 fl oz (0.23 mL), and 0.014 fl oz (0.4 mL) and 0.027 fl. oz (0.8 mL) applicator sizes

OPTION 2 for pink applicators inside CRP package: X is the liquid amount of one applicator; Y is the number of applicators that are in the carton; Z is the sum of the liquid amounts; Y can be 3 and 6 for the 0.0078 fl oz (0.23 mL), 0.014 fl oz (0.4 mL), and 0.027 fl oz (0.8 mL) applicator size

OPTION 3 for gray applicators inside CRP package: X is the liquid amount of one applicator; Y is the number of applicators that are in the carton; Z is the sum of the liquid amounts; Y can be 3 and 6 for the 0.0078 fl oz (0.23 mL) and 0.014 fl oz (0.4 mL) applicator size

#### {Begin Optional Active Ingredient Reference Statements}

{Note to reviewer: Text for statements in blocks 2 and 3 will only be used if text for statements in block 1 are used, and will be placed directly below text from block 1.}

- Contains the active ingredients in Advantage II {or} [Contains imidacloprid and pyriproxyfen, the active ingredients used in Advantage® II]{or} TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] contains [imidacloprid and pyriproxyfen], the active ingredients used in Advantage®II [Advantage®II Kitten] [Advantage®II Small Cat] [Advantage®II Large Cat]
- This product is not manufactured by Bayer Healthcare LLC, the makers of Advantage®II {OR} [Advantage®II is a registered trademark of Bayer Healthcare LLC] {OR}
   TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [This product] is not manufactured [or distributed] by Bayer Healthcare LLC, the makers of Advantage® II [Advantage® II Kitten] [Advantage® II Small Cat] [Advantage® II Large Cat]
- 3. [Advantage<sup>®</sup> II [Advantage<sup>®</sup> II Kitten] [Advantage<sup>®</sup> II Small Cat] [Advantage<sup>®</sup> II Large Cat] is a registered trademark of Bayer Healthcare LLC.]

[End Optional Active Ingredient Reference Statements] {END – FRONT PANEL OF CARTON}

#### {BACK PANEL OF CARTON/SIDE PANEL OF CARTON}

[The active ingredients in TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [this product] are imidacloprid and pyriproxyfen. This product is formulated to control fleas on cats. TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][1][one] month][30 days].]

#### READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON CATS AND KITTENS 8 WEEKS OF AGE OR OLDER.

**FIRST AID** 

If In Eyes		
<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> </ul>		
• 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 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 the poison control center or doctor.		
<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>		
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 advice.		
Note to Physician		
Treat the patient symptomatically.		
HOT LINE NUMBER		
Have the product container or label with you when calling a poison control center or doctor, or		
going for treatment. You may also contact 1-800-775-9416 for emergency medical treatment		
information.		

#### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS. WARNING.** Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS. For external use on cats only.** Individual sensitivities may occur after using ANY pesticide product for cats. 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. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats.

# **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

#### **Restrictions:**

• DO NOT ALLOW CHILDREN TO APPLY PRODUCT.

- Do not use on animals other than cats.
- Do not allow your cat to ingest this product.
- Do not reapply for [[four] [4] weeks] [30 days].
- Do not apply to cats weighing less than [2] [5] [9] lbs. Do not apply to cats less than 8 weeks old.
- Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat.
- Cats should be dry prior to application and remain dry for 24 hours after application.
- Use entire contents of applicator on each cat. Do not split one applicator between two cats. Do not use multiple applicators on one cat.
- Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.
- Do not apply more than one applicator per treatment for one cat regardless of the cat's weight.

How to Open: See label insert for complete instructions on how to open.

#### How to Apply:

[Apply entire content between shoulder blades]



- 1. Hold cat with one hand and use the other hand to apply the solution.
- 2. Hold applicator facing away from you and your cat's eyes, invert the applicator and use the narrow end to part the cat's hair.
- 3. Squeeze applicator firmly to apply all of the solution [on] [to] the cat's skin as a spot between the shoulder blades.

#### {For cartons containing 0.23 mL (0.0078 fl oz) applicator}

# Only For Cats Weighing 2 [-][to] 5 lbs. Do not apply to Cats weighing less than 2 lbs or less than 8 weeks old.

**[including small cats or kittens, only 8 weeks or older]** Apply one applicator 0.23 mL (0.0078 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

#### {For cartons containing 0.4 mL (0.014 fl oz) applicator}

# Only For Cats Weighing 5 [-][to] 9 lbs. Do not apply to Cats weighing less than 5 lbs. or less than 8 weeks old.

**[including small cats or kittens, only 8 weeks or older]** Apply one applicator 0.4 mL (0.014 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

#### {For cartons containing 0.8 mL (0.027 fl oz) applicator}

Only For Cats Weighing Over 9 lbs. Do not apply to cats weighing less than 9 lbs. Do not use more than one applicator on cats greater than 9 lbs. Apply one applicator 0.8 mL (0.027 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

#### FREQUENCY OF APPLICATION

[Use TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[ this product] monthly for control of flea[s] [infestations].]

[[Studies show that] TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] kills fleas within 12 hours of application and [lasts {or} protects] for [up to] [[four][4] weeks][30 days][one month].]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas on [cats][kittens] [for [up to] [[four][4] weeks][30 days][one month]].]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] [targets multiple flea life stages] [and] [kills flea eggs and larvae before they develop into biting adults].]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] breaks the flea life cycle by killing flea eggs, flea larvae, and adult fleas.]

[Apply monthly for effective flea control.]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] is waterproof 24 hours after application and remains effective, even after water immersion or exposure to sunlight [and][or] [rain]. Allow treated area to dry thoroughly before getting wet.]

[Allow treated area to dry thoroughly.]

## STORAGE AND DISPOSAL

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

**STORAGE:** Do not remove applicator from pack until ready to use. Store in a cool (below 77°F[/][25°C]), dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING: Non-refillable container. If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

In Case of Emergency, call: 1-800-775-9416 Non-Emergency, call: 1-844-276-3290 {Note to reviewer: If the coupon appears on the outside of the package, it will not obscure mandatory language}

[Coupon(s) inside or on outside of box]

If you have questions or comments about this product, please write: {Note to reviewer: the distributor name and address for product comments or questions will be noted below.}

[Tevra Brands Pet Owner Response, 9100 F St., Ste. 200, Omaha NE 68127]

Lot No. [Distributed by:] [Manufactured for:] Tevra Brands, LLC Omaha, Nebraska, 68127

EPA Reg. No. 92413–10 EPA Est. No. [BAR CODE AREA]

{Note to reviewer: A box labeled "Side effects" will be at the lower right hand corner of the back panel.}

**Side Effects**: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side

effects occur, consult your veterinarian or call 1-800-775-9416. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

{END - BACK/SIDE PANEL OF CARTON}

#### Cats Spot On

#### Imidacloprid + Pyriproxyfen

{OPTION 1 (CLEAR CRP APPLICATOR AS SINGLES OR AS STRIPS OF 3 AND 4): LABEL ON EACH INDIVIDUAL APPLICATOR}

TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats 2-5 [5-9] [>9 lbs] lbs. ≥ 8 wks Imidacloprid 9.10%, Pyriproxyfen 0.46% 0.0078 fl oz [0.014 fl oz][0.027 fl oz] Keep Out of Reach of Children Warning Read Entire Label Before Use EPA Reg. No. 92413 – 10 Lot # For external use on cats only

# {OPTIONS 2 AND 3 (PINK AND GRAY TUBES INSIDE CRP PACKAGE, IN STRIPS OF 3): LABEL ON BACK OF EACH OUTER BLISTER PACKAGE}

TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats 2-5 [5-9] [>9 lbs] lbs.  $\geq$  8 wks Imidacloprid 9.10%, Pyriproxyfen 0.46% 0.0078 fl oz {[0.014 fl oz] [0.027 fl oz] {For Pink applicators} 0.0078 fl oz [0.014 fl oz] {For Gray applicators} Keep Out of Reach of Children Warning Read Entire Label Before Use EPA Reg. No. 92413 – 10 Lot # For external use on cats only

PEEL FOIL DOWN

TO OPEN:

Use scissors to cut along the line shown above. Peel foil down completely for access to the tube. {[RM: option for adding date of current label]}

# {OPTIONS 2 AND 3 (PINK AND GRAY TUBES INSIDE CRP PACKAGE, STRIPS OF 3): LABEL ON EACH INDIVIDUAL APPLICATOR}

TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats 2-5 [5-9] [>9 lbs] lbs.  $\geq$  8 wks Imidacloprid 9.10%, Pyriproxyfen 0.46% 0.0078 fl oz {[ 0.014 fl oz][0.027 fl oz] Keep Out of Reach of Children Warning Read Entire Label Before Use EPA Reg. No. 92413 – 10 Lot # For external use on cats only **{END – LABEL ON INDIVIDUAL APPLICATOR OR BACK OF EACH BLISTER PACKAGE}** 

#### **READ ENTIRE LABEL BEFORE EACH USE.**

#### USE ONLY ON CATS AND KITTENS 8 WEEKS OF AGE OR OLDER weighing 2-5[5-9][>9] lbs.

# {Only one of the following statements will appear prominently on appropriate weight band market label enclosed in a box, as required per Agency's pet spot-on mitigation measures:}

For use ONLY on cats [&][and] kittens [weighing] 2 -[to] 5 lbs. and over 8 weeks [old][of age] [or older] {0.23 ml size package} {OR} For use ONLY on cats [&][and] kittens [weighing] 5 -[to] 9 lbs. and over 8 weeks [old][of age] [or older]{0.40 ml size package} {OR} ONLY for cats [&][and] kittens over 8 weeks [old][of age][or older] and [weighing] 2 -[to] 5 lbs {0.23 ml size package}. {OR} ONLY for cats [&][and] kittens over 8 weeks [old][of age] [or older] and [weighing] 5 -[to] 9 lbs {0.40 ml size package}. For use ONLY on cats [&][and] kittens [weighing] [more than][over][>] 9 lbs. and over 8 weeks [old][of age][or older] {0.80 ml size package} {OR}

ONLY for cats [&][and] kittens over 8 weeks [old][of age][and older] and [weighing] [more than] [over][>] 9 lbs {0.80 ml size package}.

{following text will be in addition to the above required language}

Small Cats {only for use on label for 2-5 lbs and 8 weeks or older product} Medium Cats {only for use on label for 5-9 lbs and 8 weeks or older product} Large Cats {only for use on label for >9 lbs and 8 weeks or older product}

#### **ACTIVE INGREDIENTS:**

Imidacloprid	
Pyriproxyfen	0.46%
OTHER INGREDIENTS.	
TOTAL:	100.00%

{Note to reviewer: Font size of the KOOROC statement and Signal word will be in compliance with Label Review Manual Ch. 3.}

# KEEP OUT OF REACH OF CHILDREN WARNING

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FIRST AID		
If In Eyes		
•	Hold eye open and rinse slowly and gently with water for 15-20 minutes.	
•	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.	
•	Call a poison control center or doctor for treatment advice.	
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 the poison control center or doctor.	

• Do not give anything by mouth to an unconscious person.

#### 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 advice.

#### HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-775-9416 for emergency medical treatment information.

#### NOTE TO PHYSICIAN

Treat the patient symptomatically.

### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS. WARNING.** Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS. For external use on cats only.** Individual sensitivities may occur after using ANY pesticide product for cats. 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. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats.

**Side Effects**: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-775-9416. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

# **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

#### **Restrictions:**

- DO NOT ALLOW CHILDREN TO APPLY PRODUCT.
- Do not use on animals other than cats.
- Do not allow your cat to ingest this product.
- Do not reapply for four [4] weeks][30 days].
- Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 2 [5] [9] lbs.
- Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat.
- Cats should be dry prior to application and remain dry for 24 hours after application.
- Use entire contents of applicator on each cat. Do not split one applicator between two cats. Do not use multiple applicators on one cat.
- Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.
- Do not apply more than one applicator per treatment for one cat regardless of the cat's weight.

[The active ingredients in TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[this product] are imidacloprid and pyriproxyfen. This product is formulated to control fleas on cats. TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] kills fleas within 12 hours and prevents further flea infestations for [up to] 4[four]weeks[[1][one] month][30 days].]

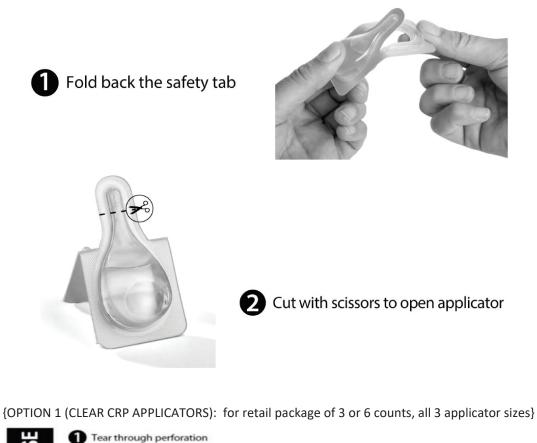
#### How to Open:

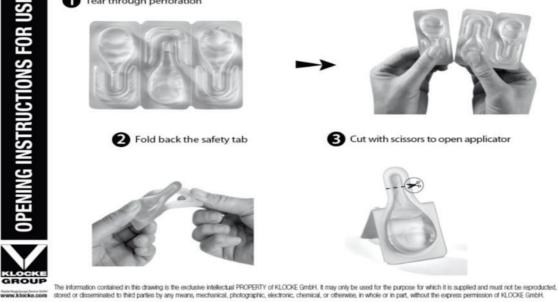
#### [Clip. Part. Squeeze.]

[Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats where it needs to be.]

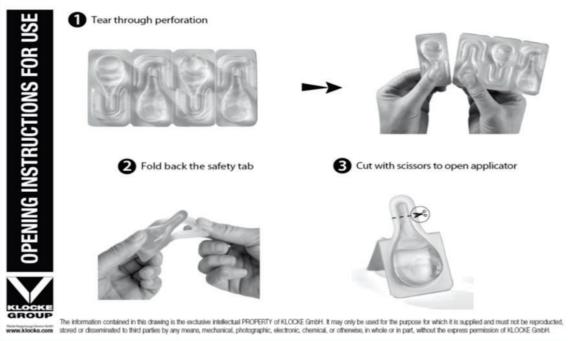
#### [Application Instructions]

#### {OPTION 1 (CLEAR CRP APPLICATORS): for retail packages of 1 count, 3-count, and 4-count:}





{OPTION 1 (CLEAR CRP APPLICATORS): for retail package of 4 or 8 counts, all 3 applicator sizes}



{OPTIONS 2 and 3: Pink applicators inside CRP package for retail package of 3 or 6 count, all 3 applicator sizes, and Gray applicators inside CRP package for retail package of 3 or 6 count AND only for 0.23 mL and 0.4 mL sizes}

TO OPEN:

- 1. Bend at perforation and tear off first tube.
- 2. Use scissors to cut along the dotted line.
- 3. Peel foil down completely for access to the tube.

#### [Apply entire content between shoulder blades]



How to Apply:

- 1. Hold cat with one hand and use the other hand to apply the solution.
- 2. Hold applicator facing away from you and your cat's eyes, invert the applicator and use the narrow end to part the cat's hair.
- 3. Squeeze applicator firmly to apply all of the solution on [to] the cat's skin as a spot between the shoulder blades.

#### {For cartons containing 0.23 mL (0.0078 fl oz) applicators}

# Only For Cats Weighing 2 -[to] 5 lbs. Do not apply to Cats weighing less than 2 lbs or less than 8 weeks old.

[including small cats or kittens, only 8 weeks or older] Apply one applicator 0.23 mL (0.0078 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

{For cartons containing 0.4 mL (0.014 fl oz) applicators}

Only For Cats Weighing 5 -[to] 9 lbs. Do not apply to Cats weighing less than 5 lbs or less than 8 weeks old.

[including small cats or kittens, only 8 weeks or older] Apply one applicator 0.4 mL (0.014 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

{For cartons containing 0.8 mL (0.027 fl oz) applicators}

Only For Cats Weighing Over 9 lbs. Do not apply to cats weighing less than 9 lbs. Do not use more than one applicator on cats greater than 9 lbs. Apply one applicator 0.8 mL (0.027 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

#### FREQUENCY OF APPLICATION

[Use TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[this product] monthly for control of flea[s] [infestations].]

[[Studies show that] TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] kills fleas within 12 hours of application and [lasts {or} protects] for [up to] four[4] weeks][30 days][one month].]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] kills reinfesting fleas within 2[two] hours and prevents further infestations of fleas on cats[kittens] [for [up to] four[4] weeks][30 days][one month]].]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] targets multiple flea life stages [and kills flea eggs and larvae before they develop into biting adults].]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] breaks the flea life cycle by killing flea eggs, flea larvae, and adult fleas.]

[Apply monthly for effective flea control.]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[This product] is waterproof 24 hours after application and remains effective, even after water immersion or exposure to sunlight [and][or] [rain]. Allow treated area to dry thoroughly before getting wet.]

[Allow treated area to dry thoroughly.]

## STORAGE AND DISPOSAL

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

STORAGE: Do not remove applicator from pack until ready to use. Store in a cool (below 77°F[/][25°C]), dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Non-refillable container. If empty: Do not reuse or refill this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

#### **WARRANTY**

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to be adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Tevra is committed to providing high quality products. To the extent consistent with applicable law, Tevra makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Tevra, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: Tevra Brands Pet Owner Response, 9100 F St., Suite 200, Omaha, NE 68127 [Satisfaction Guaranteed.] [If you are not satisfied, we will make it right with a replacement or refund.] In Case of Emergency, call: 1-800-775-9416 Non-Emergency, call: 1-844-276-3290 [Distributed by:] [Manufactured by:] Tevra Brands, LLC Omaha, Nebraska, 68127 **{END OF PACKAGE INSERT LABEL}** 

{Note to Reviewer: the icons below may appear on the label where the word "[icon]" appears}

Optional graphics that may appear anywhere on the label:



# {START – PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR REMINDER CARD OR CALENDAR STICKERS OR MAGNET}

#### [Clip. Part. Squeeze.]

[Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats[this product] where it needs to be.]

#### [Application Instructions]

#### How to Open:

See package insert for opening instructions.

#### How to Apply:

- 1. Hold cat with one hand and use the other hand to apply the solution.
- 2. Hold applicator facing away from you and your cat's eyes, invert the applicator and use the narrow end to part the cat's hair.
- 3. Squeeze applicator firmly to apply all of the solution on [to] the cat's skin as a spot between the shoulder blades.

Look at the Label [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh your cat
- [3] Do NOT use this product on dogs
- [4] Do NOT treat with more than one pesticide product at a time

Your cat must be dry at the time of application and remain dry for 24 hours after application. [5] Separate the treated cat from all other animals after [treatment {or} application] to avoid chance of ingestion until product has dried

[6] Do NOT split applicator between cats [and use the ENTIRE applicator contents]

#### [Monthly reminder card]

TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats

[Monthly reminder card]

2[3][4][5][6][12][24]Month Treatment [Application] Tracker[Carecard]

[For year round protection apply TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats monthly.]

[Cat's Name {Empty blank for owner to fill in name}] [Cat's Weight {Empty blank for owner to fill in name}]

First[1st] [Second][2nd] [Third][3rd] [Fourth][4<sup>th</sup>] [Fifth][5<sup>th</sup>] [Sixth][6<sup>th</sup>] [Seventh][7<sup>th</sup>]

[Eighth][8<sup>th</sup>] [Ninth][9<sup>th</sup>] [Tenth][10<sup>th</sup>] [Eleventh][11<sup>th</sup>] [Twelfth][12<sup>th</sup>] Dose [Treatment]

[Application]{Empty blank for owner to fill in date (Date: MM/DD/YY)}]

Application Date [Date of Application]

## [Calendar stickers with TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats]

[Place stickers on your calendar as a reminder to reapply TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats in 30 days.]

[Monthly Application Reminder Magnet {image of reminder magnet}]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats to your cat]

## [Magnet]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days, the reminder light will blink, reminding you to reapply TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

{END – PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR REMINDER CARD OR

### CALENDAR STICKERS OR MAGNET}

### [Flea Marketing Claims]

[Prevents further flea infestation for up to four[4] weeks][1 month] with [just] one treatment] [Prevents further flea infestation for up to four[4] weeks][1 month] with [just] one application] [One treatment prevents further flea infestation for a month]

[Prevents flea re-infestations for 30 days [1 month]]

[For the prevention and treatment of Flea Infestations on cats[kittens]]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats Prevents further flea infestation for four[4] weeks][1 month]]

[Kills fleas within 12 hours on cats [and prevents further infestations for up to 4[four]

weeks][[1][one][a] month]]

[Kills fleas within 12 hours [of application][on cats]]

[Kills reinfesting fleas within 2 hours]

[Kills [adult] fleas so they can't lay eggs]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the for disc a structure of fleas an actual

feeding activity of fleas on cats]

[Apply monthly [for effective flea control]]

[Apply monthly [to control and prevent fleas]]

[Apply monthly treatments for optimal control and prevention of fleas]

[Kills fleas]

[Kill fleas within 12 hours, continues to kill for up to 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis]]

[Controls existing flea infestation on cats[kittens] by killing adult fleas]

[Active against fleas]

[Kills fleas on cats and kittens over 8 weeks [old][of age] and 2-5[ 5-9] [over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Kills fleas on cats weighing 2 to 5 [5 to 9] [over 9] lbs and over 8 weeks old {weight range dependent upon appropriate ml/fl oz package size}]

[Begins[Starts] working through contact]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats Offers protection for cats[kittens] against fleas] [Flea control for cats [and kittens] over 8 weeks [old][of age] and 2-5[5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Once per month topical flea treatment for cats]

[Monthly topical flea treatment for cats]

[Once-a-month topical treatment for cats]

[Flea control for cats and kittens over 8 weeks [old][of age] and 2-5[5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Flea control for cats and kittens 8 weeks [of age] or older and 2-5[5-9] [over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Once per month][Monthly] topical flea treatment for cats over 8 weeks [old][of age] and 2-5[5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Once per month][Monthly] topical flea treatment for cats 8 weeks [of age] or older and 2-5 [5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Once-a-month topical [treatment] [for] flea prevention and treatment for cats 8 weeks [of age] or older and 2-5[5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [This product] is for the treatment and prevention of fleas on cats over 8 weeks [old][of age] and 2-5[5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [This product] is for the treatment and prevention of fleas on cats 8 weeks [of age] or older and 2-5[5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size} [Prevents and treats flea[s] [infestations] on cats[kittens]] [Kills reinfesting fleas on cats within 2 hours] [For the prevention and treatment of Flea Infestations] [TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats Prevents further flea infestation for up to four[4] weeks][[1][one][a] month]] [Controls existing infestations on cats[kittens] by killing adult fleas for 30 days] [Controls existing flea infestations on cats and protects against further infestations] [Use of TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [this product] kills fleas which may cause flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]] [Use of TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [this product] kills fleas which may cause flea bite hypersensitivity [and][or] flea allergy dermatitis [FAD]] [Monthly treatment with TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [this product] kills fleas which may cause flea bite hypersensitivity [and][or] flea allergy dermatitis [FAD]] [May be used year-round for control of fleas]

### [IGR Marketing Claims]

[Prevents flea eggs from hatching]

[Prevents flea eggs from developing into [biting] adult fleas]

[Prevents the development of flea eggs into [biting] adult fleas]

[Prevents the development of flea larvae into [biting] adult fleas]

[Controls existing flea eggs]

[Kills flea eggs]

[Breaks the flea life-cycle] [pictogram of flea life cycle]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [This product] contains Pyriproxyfen [PPF] [an insect growth regulator (IGR)] to kill flea eggs [and protect against reinfestation]]

[Targets multi-stages of the flea lifecycle]

[Controls multi-stages of flea lifecycle]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [This product] is a flea ovicide, larvicide, and adulticide]

[Provides multi-stage flea control]

[Kills [flea eggs and] flea larvae]

[Breaks the flea life cycle]

[Prevents multi-stages of the flea life cycle from developing]

[Provides flea prevention on cats[kittens]]

[Provides flea control on cats[kittens]]

[TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [This product] inhibits the immature flea life stages (except pupae) from developing, preventing them from becoming [biting] adult[s] [fleas]] [Controls existing flea eggs and fleas and prevents future infestations for 4 weeks [1 month] [30 days]]

[Monthly treatment controls existing flea eggs and fleas and prevents future infestations for 4 weeks [1 month] [30 days]]

## [COMBO Marketing Claims]

[2-way protection kills adult fleas and flea eggs]

[[2-Way] Protection against adult fleas and flea eggs for up to 1 Month]

[3-way protection kills adult fleas, larvae and eggs]

[Kills flea eggs, larvae, and [adult] fleas]

[Kills [adult] fleas, [and] flea eggs, [and flea larvae]]

[Kills [adult] fleas, flea eggs and flea larvae for up to four [4] weeks][1 month]]

[Kills [adult] fleas, larvae, and eggs [, providing three-way protection]]

#### All Other Marketing Claims]

[Apply to [cats and] kittens over 8 weeks old and 2-5[5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size} [Apply to [cats and] kittens 8 weeks or older and 2-5[5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size} [[Formulated for] Cats and Kittens Over 8 Weeks Old[of Age] and 2-5[5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size} [[Formulated for] Cats and Kittens 8 Weeks [of Age] or Older and [2-5][5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size} [Can be used on kittens over 8 weeks [old][of age] {or} [8 weeks [of age] or older] and 2-5[5-9][over 9] lbs[pounds] {weight range depends upon appropriate ml/fl oz package size} [Convenient] [Convenient, easy to apply topical solution] [Starts working through contact] [Long-lasting for up to one month] [Works for up to 1 month[30 days] [Easy No-spill Applicator[s]] [Easy application] [Easy to apply product] [Easy to Use [Applicator]] [Waterproof 24 hours after application] [Kills fleas even if your cat gets wet] [Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to [sunlight] [and][or] rain] [Fragrance[-]free] [Once a month treatment] [Apply once every 4 weeks[month] [30 days]!] [4 Week Dose!] [1 Month Dose!] [30 Day Dose!] [For year-round protection, apply TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats [this product] monthly] [One applicator] [1 Month Supply] [Three applicators] [3 Month Supply] [Four applicators] [4 Month Supply] [Six applicators] [6 Month Supply] [Eight applicators] [8 Month Supply] [Direct to skin applicators] [Easy to Use applicators] [No-mess applicators] [Clip-tip design applicators][!]]

#### [Consumer Value Marketing Claims]

{Note to reviewer: If the coupon appears on the outside of the package, it will not obscure
mandatory language. Stacking/wrapping or combining packages for Value marketing will not obscure
mandatory language.}
[Coupon Inside]
[Save Now!]
[Club Pack - [8][6] Month Supply]
[Value Size]
[Club Size]

[Bonus Size] [Club Pack] [Great Value] [Better Value] [Bonus Pack] [Bonus Buy] [[1][4][6][8] pack] [Twin Pack] [Try Now, Save Later!]

{Note to reviewer: Combinations will correspond to net contents (i.e., number of applicators). All applicators must be included inside the box/carton. Buying a larger pack reduces the price of the applicators therein due to economy of scale. No additional applicators are provided. Only existing package configurations will be used for these claims (i.e, 1, 3, 4, 6, 8, depending on the applicator)}  $[(x) + (x) bonus pack!] \{x = 1, 2, 3, etc.\}$ [Buy more and save!] [Buy X Get Y Free] {x = 1, 2, 3, etc.; y is > x and = 2, 3, 4, etc.} [Buy 3 get 1 free] [Buy 2 cartons get 1 FREE] [Buy 4 cartons get 2 FREE] [50% FREE!] [50% More Free] [BOGO] [BUY 1 [applciator][carton] get 1 [applciator][carton] 50% OFF] [BUY 1 Get 1 FREE] [(x)% (More) (Free)!] [33% more free] [(x) Dose(s) Free!] [(x) Day(s) (Free)!] [(x) Month(s) Free!] [(x) Day(s) of treatment- Free!] [(x) Applicator(s) Free!] [(x) Application(s) Free!]

#### [ABNs]

Vetality Activate Plus for Cats	Vetality Activate Plus Topicals for Cats
TevraPet Activate II for Cats	TevraPet Activate II Topicals for Cats
Vetality Avantect Plus for Cats	Vetality Avantect Plus Topicals for Cats
Vetality Avantect II for Cats	Vetality Avantect II Topicals for Cats
Vetality Activate II for Cats	Vetality Activate II Topicals for Cats
Vetality Advanced II for Cats	Vetality Advanced II Topicals for Cats
Activate II for Cats	Activate II Topicals for Cats
Activate Plus for Cats	Activate Plus Topicals for Cats
Tevrapet Avanta II for Cats	Tevrapet Avanta II Topicals for Cats
Tevrapet Avenger II for Cats	Tevrapet Avenger II Topicals for Cats
Tevrapet Advanced II for Cats	Tevrapet Advanced II Topicals for Cats
Tevrapet Avante II for Cats	Tevrapet Avante II Topicals for Cats
Vetality Avanta II for Cats	Vetality Avanta II Topicals for Cats
Vetality Avenger II for Cats	Vetality Avenger II Topicals for Cats
Vetality Avante II for Cats	Vetality Avante II Topicals for Cats
Vetality Avant II for Cats	Vetality Avant II Topicals for Cats
Vetality Aventect II For Cats	Vetality Aventect II Topicals For Cats
Vetality Advocate II for Cats	Vetality Advocate II Topicals for Cats

Avante II for Cats	Avante II Topicals for Cats
Avanta II for Cats	Avanta II Topicals for Cats
Avenger II for Cats	Avenger II Topicals for Cats
Avant II for Cats	Avant II Topicals for Cats
Aventect II for Cats	Aventect II Topicals for Cats
Advocate II for Cats	Advocate II Topicals for Cats
Tevrapet Advocate II for Cats	Tevrapet Advocate II Topicals for Cats
AventSpot II for Cats	AventSpot II Topicals for Cats
ActiSpot II for Cats	ActiSpot II Topicals for Cats
Tevrapet ACTISPOT II for Cats	Tevrapet ACTISPOT II Topicals for Cats
Advotect II for Cats	Advotect II Topicals for Cats
Tevrapet Advotect II for Cats	Tevrapet Advotect II Topicals for Cats
Evergreen II Spot on for Cats	ActiGuard II for Cats
Avantect II for Cats	Tevrapet ActiGuard II for Cats
Vetality ACTISPOT II for Cats	Vetality ActiGuard II for Cats
Vetality Advotect II for Cats	Evergreen II Topicals for Cats
TevraPet PROACT for Cats	Vetality ACTISPOT II Topicals for Cats
	Vetality Advotect II Topicals for Cats