

U.S. ENVIRONMENTAL PROTECTION AGENCY

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

NOTICE	OF	PES'	ΓΙΟΙ	DE:

X Registration
Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

92413-13

11/4/19

Term of Issuance:

Conditional, Time-Limited Expires: 11/04/2021

Name of Pesticide Product:

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs

Name and Address of Registrant (include ZIP Code):

Tevra Brands, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. Ct., NW Gig Harbor, WA, 98332

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 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). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	Date:	
VE	11/4/19	
Venus Eagle, Product Manager 01 Invertebrate-Vertebrate Branch 3, Registration Division (7505P)		

- 2. This registration is time-limited and expires 11/04/2021.
- 3. At least three months before your intended sale/distribution date, submit a mock up copy of the label for review and approval. To avoid multiple rounds of review at the state level, EPA recommends waiting for the Agency's approval of the mock up before seeking registration from states. You may not sell/distribute this product until the Agency approves the mock up copy of the label. Once the mock up label is approved, you must inform the Agency when the product is first released for shipment.
- 4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. 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
- 5. 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 cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs 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, as 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, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- 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.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

- 6. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
 - a. Imidacloprid GDCI-129099
 - b. Imidacloprid EDSP-129099
 - c. Pyriproxyfen GDCI-129032
 - d. Pyriproxyfen EDSP-129032

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

7. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

- 8. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 92413-13."
- 9. Submit one copy of the final printed label for the record before you release the product for shipment.

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 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.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under 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.

Please note that the record for this product currently contains the following CSFs:

• Basic CSF dated August 9, 2019

If you have any questions, please contact Dee Colby by phone at 703-347-8657, or via email at colby.deanna@epa.gov.

Enclosure: stamped label

[Note to reviewer: [Text] in brackets denotes optional text].

[Note to reviewer: {Text} in braces denotes notes to reviewer or location of text in the final label.]

{Tevra Master Label} (FRONT PANEL OF CARTON)

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs

{Alternate Brand Names:

TevraPet ActiSpot II for Small Dogs, TevraPet ActiSpot II for Medium Dogs, TevraPet ActiSpot II for Large Dogs, TevraPet ActiSpot II for Extra Large Dogs, TevraPet ActiSpot II for Dogs. Vetality Avantect for Small Dogs, Vetality Avantect for Medium Dogs, Vetality Avantect for Large Dogs, Vetality Avantect for Extra Large Dogs, Vetality Avantect for Dogs, Vetality Advotect II for Dogs, Vetality Advotect II for Small Dogs, Vetality Advotect II for Medium Dogs, Vetality Advotect II for Large Dogs, Vetality Advotect II for Extra Large Dogs}

{Market Label-the word Dog will be at least 40-75% in height of the largest letter in the primary brand name.}

{Market Label-a large clear picture of a dog in the respective weight range will be on the front panel of the label for the product as packaged.)

(Only one of the following statements will appear on appropriate weight band market label on front panel as required per Agency's pet spot-on mitigation measures:}

For use ONLY on dogs [[&][and] puppies] [weighing] 3-[to] 10 lbs. and over 7 weeks old[of age] or older {0.4 ml size package}

For use ONLY on dogs [[&][and] pupples] [weighing] 11 -[to] 20 lbs. and over 7 weeks old[of age] or older {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 -[to] 55 lbs. and over 7 weeks old [of age] or older {2.5 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] [more than][over]> 55 lbs. and over 7 weeks [old][of age] or older {4.0 ml size package}

{icon size is 1.5 cm x 1.5 cm, black on yellow background located in the lower right corner of package} DO NOT USE ON CATS.

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

Small Dogs (only for use on label for 3-10 lbs and 7 weeks or older product) Medium Dogs (only for use on label for 11-20 lbs and 7 weeks or older product) Large Dogs (only for use on label for 21-55 lbs and 7 weeks or older product) Extra Large Dogs (only for use on label for >55 lbs and 7 weeks or older product)

ACTIVE INGREDIENTS:

Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS:	90.44%
TOTAL	100.00%1

KEEP OUT OF REACH OF CHILDREN CAUTION

ACCEPTED

Nov 04, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 92413-RG

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

[See back panel for First Aid, Precautionary Statements and Directions for Use. For all information including Storage and Disposal see package insert inside.]

NET CONTENT: X fl oz [Y – X fl oz applicators]

[Z fl oz; Y applicators - 0.014 fl oz (0.4 mL)]

[Z fl oz; Y applicators - 0.034 fl oz (1.0 mL)]

[Z fl oz; Y applicators - 0.085 fl oz (2.5 mL)]

[Z fl oz; Y applicators - 0.135 fl oz (4.0 mL)]

{Note to reviewer:

Clear CRP applicators in single count: 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; for single count, Y can be 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 for all fill volumes

{BACK PANEL}

The active ingredients in Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [this product] are imidacloprid and pyriproxyfen. This product is formulated to control fleas [adult fleas, flea eggs, and flea larvae] on dogs. Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [This product] kills fleas within 12 hours and prevents further flea infestations on dogs for 4[four weeks[1][one] month][30 days].

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES 7 WEEKS OF AGE OR OLDER.

FIRST AID		
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 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. 	
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 pat	ient symptomatically.	

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS.

CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes and 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 dogs only. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs.

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 DOG, 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 dogs.
- Use only on dogs 7 weeks and older and weighing [3-10][11-20][21-55][>55] lbs.
- Do not allow your dog to ingest this product.
- Do not reapply for four[4] weeks[30 days]
- Use entire contents of applicator on each dog. Do not split one applicator between dogs.
 Do not use multiple applicators on one dog.
- Dog must be dry prior to application and remain dry for 24 hours after application.
- Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.
- Separate the treated dog from all other dogs and cats 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.

{Side Effects box to be located on label above the cat prohibition icon/text all on the lower right-hand side of the back panel}

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian or call 1-800-775-9416.

{Do Not Use on Cats box will be located immediately below the Side Effects box on the back panel. Icon will be yellow with black images and text.

{Graphic icon:} {icon size will be 1.5 cm x 1.5 cm}

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[Distributed by:] [Manufactured by:] Tevra Brands, LLC 9100 F Street, Suite 200 Omaha, NE 68127 EPA Reg. No. 92413-EPA Est. No.

[BAR CODE AREA]

Lot No.

{PACKAGE INSERT}

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs

{Only one of the following statements will appear on appropriate weight band market label on front of package insert as required per Agency's pet spot-on mitigation measures:}

For use ONLY on dogs [[&][and] puppies] [weighing] 3 -[to] 10 lbs. and over 7 weeks old[of age] or older {0.4 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 11 -[to] 20 lbs. and over 7 weeks old[of age] or older {1.0 ml size package}

For use ONLY on dogs [[&][and] puppies] [weighing] 21 -[to] 55 lbs. and over 7 weeks old[of age] or older {2.5 ml size package}

For use ONLY on dogs [[&][and] pupples] [weighing] [more than][over] > 55 lbs. and over 7 weeks old[of age] or older {4.0 ml size package}



{icon size is 1.5 cm x 1.5 cm, black on white background} DO NOT USE ON CATS.

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

Small Dogs {only for use on label for 3-10 lbs and 7 weeks or older product} Medium Dogs {only for use on label for 11-20 lbs and 7 weeks or older product} Large Dogs {only for use on label for 21-55 lbs and 7 weeks or older product} Extra Large Dogs {only for use on label for >55 lbs and 7 weeks or older product}

READ ENTIRE LABEL BEFORE EACH USE.

ACTIVE INGREDIENTS:

Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS:	90.44%
TOTAL	100.00%]

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
If	 Call a poison control center or doctor immediately for treatment advice.
Swallowed	 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 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.

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.

CAUTION. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes and 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 dogs only. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs.

{Side Effects box to be located on label above the cat prohibition icon/text }

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian or call 1-800-775-9416.

{Do Not Use on Cats box will be located immediately below the Side Effects box on the package insert. Icon will be black on white images and text.}

- {Graphic icon:} {icon size will be 1.5 cm x 1.5 cm}
- DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

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 DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

[The active ingredients in Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [this product] are imidacloprid and pyriproxyfen. This product is formulated to control fleas [adult fleas, flea eggs, and flea larvae] on dogs. Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [This product] kills fleas within 12 hours and prevents further flea infestations on dogs for [4]four weeks[[1][one] month][30 days].]

Restrictions:

- DO NOT ALLOW CHILDREN TO APPLY PRODUCT.
- Do not use on animals other than dogs.

- Use only on dogs 7 weeks and older and weighing [3-10][11-20][21-55][>55] lbs.
- Do not allow your dog to ingest this product.
- Do not reapply for four[4] weeks[30 days]
- Use entire contents of applicator on each dog. Do not split one applicator between dogs.
 Do not use multiple applicators on one dog.
- Dog must be dry prior to application and remain dry for 24 hours after application.
- Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.
- Separate the treated dog from all other dogs and cats 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.

How to Open:

{OPTION 1 (CLEAR CRP APPLICATORS): for retail package of 1 count:}







2 Cut with scissors to open applicator

How to Apply:

- 1. Invert applicator over dog and use open end to part dog's hair.
- 2. Squeeze applicator firmly to apply all of the solution to the dog's skin as a spot to the dog's back between the shoulder blades. [or] [apply in a stripe from the back of the neck to a point midway between the neck and tail.]

{Graphic Icon:}



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

Only For Dogs Weighing 3 -[to] 10 lbs and 7 weeks or older. Do not apply to dogs weighing less than 3 lbs.

[including small dogs and puppies, only 7 weeks or older]

Apply one applicator 0.4 mL (0.014 fl oz) directly to skin [either] [as a spot [on] [to] the dog's back between the shoulder blades] [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 1.0 mL (0.034 fl oz) applicators}

Only For Dogs Weighing 11 -[to] 20 lbs and 7 weeks or older. Do not apply to dogs weighing less than 11 lbs.

Apply one applicator 1.0 mL (0.034 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 2.5 mL (0.085 fl oz) applicators}

Only For Dogs Weighing 21 -[to] 55 lbs and 7 weeks or older. Do not apply to dogs weighing less than 21 lbs.

Apply one applicator 2.5 mL (0.085 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail].

{For cartons containing 4.0 mL (0.135 fl oz) applicators}

Only For Dogs Weighing >[greater than] 55 lbs and 7 weeks or older. Do not apply to dogs weighing less than 55 lbs. Do not use two applicators on dogs greater than 55 lbs. Apply one applicator 4.0 mL (0.135 fl oz) directly to skin [either] as a spot [on] [to] the dog's back between the shoulder blades [or] [as a [stripe][line] starting from the back of the neck to a point midway between the neck and tail].

Discard the empty applicator as described in the Storage and Disposal section. Apply monthly for optimal control of fleas.

PRODUCT INFORMATION

[Use Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs[this product] monthly for control of flea[s] [infestations on your dog].] [[Studies show that] Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs[This product] kills fleas within 12 hours of application and [lasts {or} protects [for four[4] weeks[30 days][one month].]

[Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs[This product] kills reinfesting fleas within [2][two] hours]two hours and prevents further infestations of fleas on your dog [for four[4] weeks[30 days][one month]].]

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

[Apply monthly for optimal flea control.] [Apply monthly for flea control.]

[Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs[This product] is waterproof 24 hours after application and remains effective, even after bathing, swimming, or exposure to sunlight [and][or] [rain].] [Allow treated area to dry thoroughly.]

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store only in original container in a cool [(below 77°F[/][25°C])], dry place inaccessible to children and pets.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Non-refillable container. **If empty:** Do not reuse or refill this container. 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 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 Brands is committed to providing high quality products. To the extent consistent with applicable law, Tevra Brands 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 Brands, 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, Tevra Brands, LLC., 9100 F Street, Suite 200, Omaha Nebraska 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 [Coupon(s) inside or on outside of box]

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}

[Distributed by:] [Manufactured by:] Tevra Brands, LLC 9100 F Street, Suite 200 Omaha. NE 68127 EPA Reg. No. 92413-

EPA Est. No.

[BAR CODE AREA]

Lot No.

{END PACKAGE INSERT}

{ADDITIONAL OPTIONAL FOLDED PANEL/FLAP OF BACK OF PACKAGE}

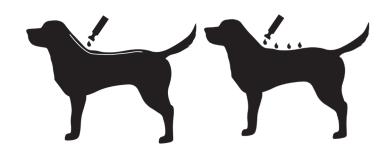
[Clip. Part. Squeeze.]

[Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven protection from fleas where it needs to be.]

How to Apply:

- 1. Invert applicator over dog and use open end to part dog's hair.
- 2. Squeeze applicator firmly to apply all of the solution [on] [to] the dog's skin as a spot to the dog's back between the shoulder blades. [or] [apply in a stripe from the back of the neck to a point midway between the neck and tail.]

{Graphic Icon:}



{APPLICATOR LABEL}

(OPTION 1 (CLEAR CRP APPLICATOR AS 1-COUNT): LABEL ON INDIVIDUAL APPLICATOR)

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [3-10][11-20][21-55][>55] lbs. ≥7 wks Imidacloprid 9.10%, Pyriproxyfen 0.46% 0.014 fl oz (or) 0.034 fl oz (or) 0.085 fl oz (or) 0.135 fl oz Keep Out of Reach of Children CAUTION Read Entire Label Before Use EPA Reg. No. 92413-Lot # For external use on dogs only [label code]



{icon will be in black and white}

THIS UNIT NOT FOR RETAIL SALE

[option for adding date of current label]

{EPA Reg. No. may be on either the front or back label} {Label code refers to Tevra's product code number assignment to each product}

(END - LABEL ON INDIVIDUAL APPLICATOR)

(MONTHLY REMINDER CARD)

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [This product]

[Monthly reminder card]

[1][2][3][4][5][6][12] Month Treatment[Application] Tracker[Carecard]

[For year-round protection, apply Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [this product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

 $[First][1st][Second][2nd][Third][3rd][Fourth][4^{th}][Fifth][5^{th}][Sixth][6^{th}][Seventh][7^{th}][Eighth][5^{th}][Sixth][6^{th}][Seventh][7^{th}][Eighth][5^{th}][Sixth][6^{th}][6^{th}][Sixth][6^{th}][6^$

[8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

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

[Application Date][Date of Application]

{CALENDAR REMINDER STICKERS}

[Calendar stickers with Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs]

[Place stickers on your calendar as a reminder to reapply Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [this product] [in 30 days.]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [this product] to your dog]

{MAGNET REMINDER}

[Monthly Application Reminder Magnet (image of reminder 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 Dogs [this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

{Optional Text for Carton Label/Package Insert}

{for use on the front, side, or back panels of the outer box or on the package insert.}

{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.}

- 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 Dogs[This product] contains [imidacloprid and pyriproxyfen], the active ingredients used in Advantage® II [Advantage® II Small Dog] [Advantage® II Medium Dog] [Advantage® II Large Dog] [Advantage® II Extra Large Dog]
- 2. 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 Dogs [This product] is not manufactured [or distributed] by Bayer Healthcare LLC, the makers of Advantage® II [Advantage® II Small Dog] [Advantage® II Medium Dog] [Advantage® II Large Dog] [Advantage® II Extra Large Dog] [Advantage® II [Advantage® II Small Dog] [Advantage® II Medium Dog] [Advantage® II Large Dog] [Advantage® II Extra Large Dog]

is a registered trademark of Bayer Healthcare LLC.] {End Optional Active Ingredient Reference Statements}

[Flea Marketing Claims]

Prevents further flea infestation for four[4] weeks[1 month][30 days] with one treatment Prevents further flea infestation for four[4] weeks[1 month][30 days] with one application One treatment prevents further flea infestation for a month

For the prevention and treatment of Flea Infestations on dogs[puppies]

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs prevents further flea infestation for four[4] weeks[1 month][30 days]

Kills fleas within 12 hours on dogs [and prevents further infestations for 4[four] weeks[[1][one][a] month][30 days]

Kills fleas within 12 hours [of application] on dogs

Kills reinfesting fleas within 2 hours [and protects your dog against further infestation] Kills fleas so they can't lay eggs

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on dogs.

Apply monthly [for effective flea control]

Apply monthly [to control and prevent fleas]

Monthly treatments are required for optimal control and prevention of fleas

Kills fleas

Kills fleas even if your dog gets wet

Kills fleas within 12 hours, continues to kill for 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, within 12 hours

Controls existing flea infestation on dogs [puppies] by killing adult fleas

Active against fleas

Kills multi-stages of fleas

Kills fleas on dogs

Kills fleas on dogs and puppies 7 weeks or older and 3-10 or 11-20 or 21-55 or over 55 pounds [lbs] {weight range depends upon appropriate ml/fl oz package size}

(Begins/Starts) working through contact

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs offers protection for dogs[puppies] against fleas

Once per month topical flea treatment for dogs

Monthly topical flea treatment for dogs

Once-a-month topical treatment for fleas on dogs

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [This product] is for the treatment and prevention of fleas on dogs

Flea control for puppies and dogs over 7 weeks old[of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}

Flea control for puppies and dog 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}

[Once per month][Monthly] topical flea treatment for dogs over 7 weeks old[of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}

[Once per month][Monthly] topical flea treatment for dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}

Once-a-month topical treatment for fleas on dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds] {weight range depends upon appropriate ml/fl oz package size} Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [This product] is for the treatment and prevention of fleas on dogs over 7 weeks [old][of age] and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [This product] is for the treatment and prevention of fleas on dogs 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}

Prevents and treats flea[s] [infestations on dogs[puppies]]

Controls existing infestations on dogs[puppies] by killing adult fleas

Use of Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [Use of this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD] Monthly treatment [with Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs][with this product] kills fleas and may reduce incidence of [flea bite hypersensitivity] [and][or] flea allergy dermatitis IFAD1

May be used year-round for control of fleas

Controls fleas, which can serve as an intermediate tapeworm host

Prevents further flea infestations on dogs for 4 weeks[30 days][1 month]

Prevents flea re-infestations on dogs[puppies] for 4 weeks[30 days][1 month]

[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

Controls existing flea eggs

Kills flea eggs

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [This product] contains Pyriproxyfen [PPF] [an insect growth regulator (IGR)] to kill flea eggs [and protect your dog against reinfestation] Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs contains an insect growth regulator[IGR] in addition to imidacloprid

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs contains the insect growth regulator Pyriproxyfen in addition to imidacloprid

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs contains an insect growth regulator[IGR] Targets multi-stages of flea lifecycle

Controls multi-stages of flea lifecycle

Kills multiple flea life stages

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [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

Kills flea eggs and flea larvae for four[4] weeks[1 month][30 days]

Prevents multi-stages of the flea life cycle from developing

Tevra Imidacloprid + Pyriproxyfen Spot On for Dogs [This product] inhibits the immature flea life stages (except pupae) from developing and preventing them from becoming [biting] adult[s] [fleas]

Monthly treatment controls existing flea eggs and fleas on dogs[puppies] and prevents future infestations

Controls existing flea eggs and fleas on dogs[puppies] and prevents future infestations for 4 weeks[30 days][1 month]

[COMBO Marketing Claims]

3-way protection kills adults, larvae and eggs

Kills flea eggs, larvae, and [adult] fleas

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

Kills [adult] fleas, flea eggs and flea larvae for four[4] weeks[1 month][30 days]

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

[All Other Marketing Claims]

Apply to [dogs and] puppies over 7 weeks old or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}

Apply to [dogs and] puppies 7 weeks or older and 3-10 or 11-20 or 21-55 or over 55 lbs [pounds] {weight range depends upon appropriate ml/fl oz package size}

Formulated for Dogs and Puppies Over 7 Weeks [Old][of Age] and 3-10 or 11-20 or 21-55 or over 55 lbs [pounds] {weight range depends upon appropriate ml/fl oz package size}

Formulated for Dogs and Puppies 7 Weeks [of Age] or Older and 3-10 or 11-20 or 21-55 or over 55 lbs [pounds] {weight range depends upon appropriate ml/fl oz package size}

Dogs and Puppies over 7 weeks [old][of age] [or] 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds] {weight range depends upon appropriate ml/fl oz package size} Can be used on puppies over 7 weeks [old][of age] [or] 7 weeks [of age] or older and 3-10 or 11-20 or 21-55 or over 55 lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}

The Only Protection From Flea Infestations You Need For Your Dog[s] When Applied Monthly! Convenient

Easy application

Easy to apply product

Easy to Use [Applicator]

Convenient, easy to apply topical solution]

Waterproof 24 hours after application

Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to sunlight [and][or] rain

Fragrance[-]free

Remains effective even after the dog swims

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 Dogs [this

product] monthly

[One applicator] [1 Month Supply] [Two applicators] [2 Month Supply] [Three applicators] [3 Month Supply] [Four applicators] [4 Month Supply] [Five applicators] [5 Month Supply] [Six applicators] [6 Month Supply] [9 applicators] [9 Month Supply] [12 applicators] [12 Month Supply]

Direct to skin applicator
Easy to Use applicator
No-mess applicator

Clip-tip design applicator[!]

[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!

Value Size

Club Size

Bonus Size

Club Pack

Great Value

Better Value

Bonus Pack

Bonus Buv

[1][2][3][4][5][6][7][8][9][10][11][12] 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, 1-12 individual applicators)}

(x) + (x) bonus pack! $\{x = 1, 2, 3, etc.\}$

Buy more and save!

Buy 3 get 1 free

Buy 4 get 1 free

33% more free {Note to reviewer: 3 + 1 applicators or 6 + 2 applicators}

25% more free {Note to reviewer: 4 + 1 applicators}

- (x) Dose(s) Free!
- (x) Month(s) Free!
- (x) Applicator(s) Free!

[New!] {only for use for 6 months from date of registration}

$\{ \mbox{OPTIONAL GRAPHICS BELOW MAY APPEAR ANYWHERE ON FINISHED LABEL OR OUTER PACKAGING:} \}$

{Examples of applicator icons}











[Adult Flea, Fleas, Flea eggs, Flea life cycle diagram, Flea Life Cycle]













