U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W.	EPA Reg. Number: 11556-144	Date of Issuance: 7/20/21	
Washington, D.C. 20460 NOTICE OF PESTICIDE: <u>X</u> Registration Reregistration	Term of Issuance: Conditional, Time-Limited Expires: 05/31/2023		
(under FIFRA, as amended)	Name of Pesticide Product: K9 Advantix II Extra Large Dog		
Name and Address of Registrant (include ZIP Code): J. Todd Frank Regulatory Affairs Consultant Bayer Health Care LLC Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390			
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/reregistration/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:		
Elizaber Fatur	7/20/21		
Elizabeth Fertich, Product Manager 04 Invertebrate & Vertebrate Branch 1, Registration Division Office of Pesticide Programs EPA Form 8570-6			

Registration Notice Conditional Time-Limited Dog Spot-On Extension v.20151203

- 2. The Agency has found your company to be in compliance with the terms and conditions for the subject product and is extending the two-year registration restriction. This registration is time-limited and expires 05/31/2023.
- 3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation information as stated in the amendment letter dated 01/19/2011 and to submit annual reports of enhanced incident and sales using EPA's standardized templates as stated in the letter dated 03/31/2021.
- 4. You are required to comply with the data requirements described in the DCI identified below:
 - a. Imidacloprid GDCI-129099-951
 - b. Imidacloprid GDCI-129099-1516
 - c. Pyriproxyfen GDCI-129032-1299

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <u>http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1</u>

5. 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 11/21/2019

If you have any questions, please contact Kaitlin Saunders by phone at 703-347-8454, or via email at Saunders.Kaitlin@epa.gov.

Reason To Issue: EPA updates.

Date: 06/21/2021 Supersedes: 06/07/2018 Page 1 of 18

NOTE TO REVIEWER: Braces "{ }" indicate notes to reviewer. Brackets "[]" indicate alternate language.

{Front Panel}

For Use ONLY on Dogs 7 Weeks and Older and Over 55 lbs.

ACCEPTED
07/20/2021
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under
EPA Reg. No. 11556-144

{A large, clear picture of a dog in the weight range for the product will be on the front panel.}

K9 Advantix[®] II Extra Large Dog

{The "Extra Large Dog" text size will be 40% to 75% of the height of the largest letter in the primary brand name.}

{Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS}

Image of tube

[1, 2, 3, 4, 6, 8, 12 or 24] monthly doses

	%
ACTIVE INGREDIENTS	By Weight

Imidacloprid.	8.80%
Permethrin*	0.44%
OTHER INGREDIENTS	40./0%
Total	100.00%

* cis/trans ratio: Max 55% (\pm) cis and min 45% (\pm) trans

Topical Prevention and Treatment of Fleas, Ticks, Mosquitoes, Biting Flies, and Lice for Monthly Use Only on Dogs and Puppies 7 Weeks of Age and Older and Weighing Over 55 lbs.

KEEP OUT OF REACH OF CHILDREN

WARNING

See back panel for First Aid, Precautionary Statements and Directions for Use. For all information, including Storage and Disposal, see insert inside carton. Reason To Issue: EPA updates.

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{Icon Size 1.5 cm X 1.5 cm cat prohibition icon shall be placed in a box located at the lower right hand corner of the front panel in yellow with black images}

{Back Panel}

K9 Advantix[®] II Extra Large Dog

{The "Extra Large Dog" text size will be 40% to 75% of the height of the largest letter in the primary brand name.}

Topical Prevention and Treatment of Fleas, Ticks, Mosquitoes, Biting Flies, and Lice for Monthly Use Only on Dogs and Puppies 7 Weeks of Age and Older and Weighing Over 55 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Fleas, Ticks, Mosquitoes, Biting Flies and Lice on Dogs

{Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS}

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 1-800-422-9874 for emergency medical treatment information. For consumer questions call 1-800-255-6826.

NOTE TO PHYSICIAN

Treat the patient symptomatically.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on skin or clothing. Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs only. Do not use on animals other than dogs. Do not use on puppies under seven (7) weeks of age or weighing less than 55 lbs. Do not get this product in dog's eyes or mouth. This product is not a substitute for prescribed heartworm preventative. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product.

{A box labeled "Side Effects" will be immediately above the cat warning box on 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 or agitation) occur, consult your veterinarian or call 1-800-422-9874.

{A "Fatality box" will be located immediately below the Side Effects box in the lower right hand corner of the back panel. The box will include $1.5 \text{ cm} \times 1.5 \text{ cm}$ cat prohibition icon and warning text in yellow and black images and text.}



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

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

Application of product must only be done indoors.

Restrictions:

- Do not allow children to apply product.
- Do not have contact or allow children to have contact with treated area until completely dry.
- Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.
- Do not get this product in your dog's eyes or allow your dog to ingest this product.
- Dogs should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].

See inside flap for HOW TO OPEN and HOW TO APPLY, or insert for full Directions for Use.

For consumer questions call 1-800-255-6826. For medical emergencies call 1-800-422-9874.

Net Contents: [1, 2, 3, 4, 6, 8, 12 or 24] Tube(s) each 0.135 fl. oz. (4.0 mL)

EPA Est. No. 11556-XXX-X

EPA Reg No. 11556-144

Manufactured For

Elanco US Inc. 2500 Innovation Way Greenfield, IN 46140

Made in Germany

{The sample package is only the one tube package size and will optionally include the text: [Sample – Not for [Re]Sale]}

{Back Panel and/or Bottom of Carton}

Lot No.

{Inside Flap of Carton}

DIRECTIONS FOR USE (continued from back panel)

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

Application of product must only be done indoors.

HOW TO OPEN



[OPTION 1: INSTRUCTIONS FOR BLISTER PACK]

- 1. Being careful not to cut close to the blister cavities, take scissors and cut off one section of the card containing a single tube.
- 2. Take the separated section, and cut into the blister cavity across the small side, close to the cap of the tube.
- 3. Peel off the foil, and take out the tube.

[OPTION 2: INSTRUCTIONS FOR SHORT NECK TUBE POUCH]

- 1. Be sure tube is at bottom of pouch.
- 2. Using scissors, cut the pouch across the top and remove tube.

[OPTION 3: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Be sure the tube is at the bottom of the pouch.
- 2. Use scissors to cut the pouch across the top, being careful not to cut the tube.
- 3. Remove the tube from the package.

HOW TO APPLY

[OPTION 1: INSTRUCTIONS FOR BLISTER PACK AND SHORT NECK TUBE POUCH]

- 1. Remove applicator tube from the package. [Use scissors and peel down foil.]
- 2. Dogs should be dry prior to application and remain dry for 24 hours after application.
- 3. Hold applicator tube in an upright position. Pull cap off tube.



- 4. Turn the cap around and place other end of cap back on tube.
- 5. Twist cap to break seal, then remove cap from tube.

6. The dog should be dry and standing for easy application. Evenly apply the entire contents of the K9 Advantix[®] II tube to four to six spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. <u>Do not get this product in your dog's eyes, or allow your dog to ingest this product.</u>



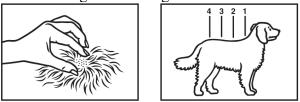
- 7. Discard empty tube as described in Storage and Disposal.
- 8. In case of severe pest infestation, re-treatment is allowable after the initial application earlier than (4) four weeks. Do not retreat more often than once every seven (7) days not to exceed 4 weekly treatments. After pest control is attained, return to a monthly retreatment schedule.

[OPTION 2: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Use only on dogs 7 weeks and older and weighing over 55 lbs. DO NOT USE ON CATS or other animals.
- 2. Dogs should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one pouch from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your dog's face and eyes. Twist the tip of the applicator to break seal.



5. The dog should be standing for easy application. In order to ensure proper application, part the hair on the dog's back between the shoulder blades. Place the tip of the tube against the dog's skin.



- 6. Gently squeeze the tube to expel a portion of the solution on the skin.
- 7. Repeat steps 5 and 6 at different points down the center of the dog's back from the shoulder blades to the tail until the tube is empty.
- 8. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. *Do not get this product in your dog's eyes or allow your dog to ingest this product.*
- 9. Discard the empty tube as described in the Storage and Disposal section.
- 10. Under normal conditions, this product is effective for a month. However, if the dog has a severe infestation, retreatment within a month may be necessary. Do not retreat more than once every seven (7) days not to exceed 4 weekly treatments. After flea control is attained, return to a monthly retreatment schedule.

{Insert}

K9 Advantix[®] II Large Dog

{The "Extra Large Dog" text size will be 40% to 75% of the height of the largest letter in the primary brand name.}

Topical Prevention and Treatment of Fleas, Ticks, Mosquitoes, Biting Flies, and Lice for Monthly Use Only on Dogs and Puppies 7 Weeks of Age and Older and Weighing Over 55 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Fleas, Ticks, Mosquitoes, Biting Flies and Lice on Dogs

{Selected optional claims bulleted here from OPTIONAL MARKETING CLAIMS}

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ACTIVE INGREDIENTS

% By Weight

Imidacloprid	8.80%
Permethrin*	0.44%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

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 1-800-422-9874 for emergency medical treatment information. For consumer questions call 1-800-255-6826.

NOTE TO PHYSICIAN

Treat the patient symptomatically.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on skin or clothing. Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs only. Do not use on animals other than dogs. Do not use on puppies under seven (7) weeks of age or weighing less than 55 lbs. Do not get this product in

Reason To Issue:EPA updates.Date: 06/21/2021Supersedes: 06/07/2018Page 9 of 18

dog's eyes or mouth. This product is not a substitute for prescribed heartworm preventative. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product.

{A box labeled "Side Effects" will be immediately above the cat warning box on 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 or agitation) occur, consult your veterinarian or call 1-800-422-9874.

{A "Fatality box" will be located immediately below the Side Effects box in the lower right hand corner of the back panel. The box will include $1.5 \text{ cm} \times 1.5 \text{ cm}$ cat prohibition icon and warning text in yellow and black images and text.}



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

For consumer questions call 1-800-255-6826. For medical emergencies call 1-800-422-9874.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

Application of product must only be done indoors.

Restrictions:

- Do not allow children to apply product.
- Do not have contact or allow children to have contact with treated area until completely dry.
- Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

- Do not get this product in your dog's eyes or allow your dog to ingest this product.
- Dogs should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].

HOW TO OPEN



[OPTION 1: INSTRUCTIONS FOR BLISTER PACK]

- 1. Being careful not to cut close to the blister cavities, take scissors and cut off one section of the card containing a single tube.
- 2. Take the separated section, and cut into the blister cavity across the small side, close to the cap of the tube.
- 3. Peel off the foil, and take out the tube.

[OPTION 2: INSTRUCTIONS FOR SHORT NECK TUBE POUCH]

- 1. Be sure tube is at bottom of pouch.
- 2. Using scissors, cut the pouch across the top and remove tube.

(OPTION 3: INSTRUCTIONS FOR LONG NECK TUBE POUCH)

- 1. Be sure the tube is at the bottom of the pouch.
- 2. Use scissors to cut the pouch across the top, being careful not to cut the tube.
- 3. Remove the tube from the package.

HOW TO APPLY

[OPTION 1: INSTRUCTIONS FOR BLISTER PACK AND SHORT NECK TUBE POUCH]

- 1. Remove applicator tube from the package. [Use scissors and peel down foil.]
- 2. Dogs should be dry prior to application and remain dry for 24 hours after application.
- 3. Hold applicator tube in an upright position. Pull cap off tube.



- 4. Turn the cap around and place other end of cap back on tube.
- 5. Twist cap to break seal, then remove cap from tube.
- 6. The dog should be dry and standing for easy application. Evenly apply the entire contents of the K9 Advantix[®] II tube to four to six pots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot

that could cause some of the solution to run off the side of the dog. <u>Do not get this</u> product in your dog's eyes, or allow your dog to ingest this product.



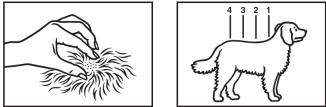
- 7. Discard empty tube as described in Storage and Disposal.
- 8. In case of severe pest infestation, re-treatment is allowable after the initial application earlier than (4) four weeks. Do not retreat more often than once every seven (7) days not to exceed 4 weekly treatments. After pest control is attained, return to a monthly retreatment schedule.

[OPTION 2: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

- 1. Use only on dogs 7 weeks and older and weighing over 55 lbs. DO NOT USE ON CATS or other animals.
- 2. Dogs should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one pouch from the carton. See "HOW TO OPEN" section.
- 4. Hold applicator tube in an upright position facing away from you and your dog's face and eyes. Twist the tip of the applicator to break seal.



5. The dog should be standing for easy application. In order to ensure proper application, part the hair on the dog's back between the shoulder blades. Place the tip of the tube against the dog's skin.



- 6. Gently squeeze the tube to expel a portion of the solution on the skin.
- 7. Repeat steps 5 and 6 at different points down the center of the dog's back from the shoulder blades to the tail until the tube is empty.

- 8. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. *Do not get this product in your dog's eyes or allow your dog to ingest this product.*
- 9. Discard the empty tube as described in the Storage and Disposal section.
- 10. Under normal conditions, this product is effective for a month. However, if the dog has a severe infestation, retreatment within a month may be necessary. Do not retreat more than once every seven (7) days not to exceed 4 weekly treatments. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

[The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with K9 Advantix[®] II rapidly kills fleas and may reduce the incidence of this condition.]

[K9 Advantix[®] II kills existing fleas on dogs after initial application within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting at least four (4) weeks. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.]

K9 Advantix[®] II is waterproof after 24 hours and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

To successfully prevent and control fleas and ticks, all dogs must be treated with their own dose of K9 Advantix II.

Apply according to label instructions, ensuring that the product is applied to the skin, not on top of the fur.

If your dog wears a decorative collar, it may be helpful to remove the collar before application, so it doesn't absorb the product.

Remember, your dog needs to be dry at the time K9 Advantix II is applied and remains dry 24 hours after application.

Even indoor dogs need protection against fleas and ticks because you or other pets in the household may bring fleas and ticks into the home. Fleas in your dog's environment can re-infest your dog. If you have a flea infestation, consider treating your home and yard with appropriate premise products to protect against fleas.

Monthly treatments are required for optimal control and prevention of fleas and ticks.

For dogs over 55 lbs., do not apply more than 1 tube per treatment.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets. Protect from freezing. **Pesticide Disposal and Container Handling**: Nonrefillable container. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available. **If partly filled**: Do not pour or dispose down-the-drain. Call your local solid waste agency or 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Elanco US Inc. warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ELANCO MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Elanco is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law, any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

For additional information visit www.petbasics.com

Manufactured for Elanco US Inc. 2500 Innovation Way Greenfield, IN 46140

Made in Germany

EPA Est. No. 11556-XXX-X EPA Reg No. 11556-144 _____

{Label on Individual Tube}

K9 Advantix[®] II Extra Large Dog

8.8% imidacloprid 44.0% permethrin 0.44% pyriproxyfen

0.135 fl. oz. (4.0 mL)

EPA Reg. No. 11556-144

Keep out of reach of children

WARNING

DO NOT USE ON CATS

Read The Entire Label Before Use

ELANCO

Lot No. 0000000

Reason To Issue: EPA updates.

Date: 06/21/2021 Supersedes: 06/07/2018 Page 15 of 18

{OPTION 1: Label on blister pack; one card containing 1, 2, 3, 4, or 6 tubes} {OPTION 2: Label on pouch containing one tube}

[Additional label text for OPTION 2: THIS UNIT NOT FOR RETAIL SALE]

K9 Advantix[®] II Extra Large Dog

For external use only on dogs and puppies 7 weeks and older and weighing over 55 lbs.

See insert for complete product information.

8.8% imidacloprid44.0% permethrin0.44% pyriproxyfen

[1, 2, 3, 4, 6, 8, 12 or 24] Tube(s) - 0.135 fl. oz. (4.0 mL)

EPA Reg. No. 11556-144

ELANCO

Lot No. 0000000



K9 Advantix II XL qa

NOTE TO REVIEWER: [Brackets indicate alternate language]

OPTIONAL MARKETING CLAIMS

- 1. For use on dogs and puppies 7 weeks of age and older and weighing over 55 lbs
- 2. K9 Advantix[®] II contains [imidacloprid], [permethrin] and [an/the] [insect growth regulator] [IGR] [pyriproxyfen]
- 3. A single topical application remains effective for [a month] [four (4) weeks]
- 4. Convenient, easy to apply topical solution
- 5. Once a month topical flea treatment for dogs 7 weeks of age or older and weighing over 55 lbs
- 6. K9 Advantix[®] II is for the prevention and treatment of fleas, ticks, biting flies, mosquitoes, and lice on dogs 7 weeks of age and older and weighing over 55 lbs
- 7. Repels and kills ticks, fleas and mosquitoes
- 8. For the treatment and prevention of flea infestations on dogs
- 9. One treatment prevents further flea infestations [for] [a month][four (4) weeks] on dogs
- 10. Kills fleas on dogs within 12 hours and continues to prevent infestations for [a month][four (4) weeks]
- 11. Repels and kills fleas so they can't lay eggs
- 12. Kills fleas [rapidly] on dogs within 12 hours of application
- 13. Stops existing flea infestations by killing adult fleas
- 14. Prevents [Stops] reinfestations by killing adult fleas so they can't lay eggs
- 15. Prevents [Stops] flea eggs from hatching [into biting adults]
- 16. Effectively breaks the flea life cycle
- 17. Flea adulticide, larvicide and ovicide.
- 18. Prevents fleas on treated dogs
- 19. Effectively targets all [life] stages of [fleas] and [ticks]
- 20. 3-way protection against fleas [kills] [controls] adults, larvae, and eggs
- 21. Prevents [Stops] development of fleas, flea eggs, pupae and larvae [for][a month][four (4) weeks]
- 22. Prevents [Stops] development of all flea stages [for] [a month][four (4) weeks]
- 23. Repels and kills all [life] stages of fleas on dogs
- 24. Prevents [Stops] flea eggs [and flea larvae] from developing into [biting][adult] fleas
- 25. Treatment with K9 Advantix[®] II kills fleas and may reduce the incidence of Flea Allergic Dermatitis [FAD]
- 26. Repels and kills ticks, including Deer ticks [that may [vector] [transmit] [carry] Lyme disease and anaplasmosis], American dog ticks [that may [vector] [transmit] [carry] Rocky Mountain spotted fever, tularemia and ehrlichiosis], Brown dog ticks [that may vector ehrlichiosis, anaplasmosis, bartonellosis, canine hemoplasmosis, babesiosis and Rocky Mountain spotted fever], and Lone Star ticks [that may [vector] [transmit] [carry] ehrlichiosis and tularemia]
- 27. Repels and kills mosquitoes for up to four weeks that may transmit [heartworm disease][*Dirofilaria immitis*], [West Nile Virus]
- 28. Repels and kills mosquitoes often before they have a chance to take a blood meal
- 29. [Prevents blood-feeding by] [Kills and repels] mosquitoes
- 30. Repels, and inhibits blood-feeding by biting flies on dogs
- 31. Repels, and prevents blood-feeding by biting flies on dogs
- 32. Repels [annoying][bothersome][nuisance] biting flies

- 33. Inhibits [annoying][bothersome][nuisance] biting flies
- 34. [Prevents][inhibits] blood-feeding by biting flies on dogs
- 35. Remains effective after bathing and/or swimming
- 36. Remains effective following swimming and/or shampooing
- 37. Kills [biting][chewing] lice on dogs
- 38. For treatment and prevention of [biting][chewing] lice [infestations] on dogs
- 39. Controls existing [biting][chewing] lice infestations on dogs
- 40. 5-way protection against fleas, ticks, biting flies, mosquitoes, and lice
- 41. Treats, prevents and controls [biting][chewing] lice [infestations]
- 42. Provides effective control of [biting][chewing] lice [infestations]
- 43. Kills [biting][chewing] lice and prevents further infestations on dogs
- 44. For treatment and prevention of infestations with [biting][chewing] lice on dogs
- 45. Waterproof after 24 hours
- 46. Remains effective after exposure to rain or sunlight
- 47. Fragrance free
- 48. Kills [and repels] [biting] mosquitoes which may cause allergic reactions in your dog such as hives or swelling.
- 49. Protect dogs by [killing][and/or] [repelling] [fleas], [ticks], [mosquitoes], [biting flies] and [lice]
- 50. Kills fleas, flea eggs and flea larvae
- 51. Kills fleas and their eggs
- 52. Protects dogs against fleas
- 53. Protects dogs against flea infestations
- 54. Prevents [establishment of] new infestations on dogs after application
- 55. Kills fleas that may cause transmission of tapeworms in dogs
- 56. Kills fleas which may cause Flea Allergy Dermatitis and flea bite anemia
- 57. Kills fleas that may cause a tapeworm [infestation][infection] in dogs
- 58. Kills fleas and ticks through contact.
- 59. Kills [stage] fleas, [stage] ticks, mosquitoes for [4 weeks][a full month]
- 60. Helps prevent [flea/tick] reinfestations on dogs for [30 days][4 weeks][a full month]
- 61. Kills fleas that can transmit tapeworms
- 62. Kills mosquitoes which can cause mosquito allergies
- 63. Flea Protection for your dog when applied monthly
- 64. Stays on, doesn't rub off
- 65. Stops and prevents [flea/tick] [infestations][reinfestations] on dogs
- 66. Helps prevent flea and tick [infestations][reinfestations] on your dog [for][30 days][1 month][4 weeks]
- 67. Kills flea eggs and flea larvae to help prevent future re-infestations on your dog
- 68. Helps prevent [stop] ticks from attaching and feeding on dogs
- 69. Protects dogs against ticks
- 70. Kills and repels ticks on dogs [that may cause tick paralysis]
- 71. Kills new fleas in 2 hours [preventing reinfestation]
- 72. [Effective] [Convenient] topical treatment against [fleas], [ticks] [and] [mosquitoes]
- 73. Protect dogs by [killing][and/or] [repelling] mosquitoes for up to four weeks that may [vector] [transmit] [carry] [*Dirofilaria immitis*] [Heartworms] [West Nile Virus].
- 74. Protect dogs by [killing][and/or] [repelling] mosquitoes for up to four weeks that may [vector] [transmit] [carry] [*Dirofilaria immitis*], which can cause heartworm disease.

- 75. Protect dogs by [killing][and/or] [repelling] fleas that may [vector] [transmit] [carry] [tapeworms] [Bartonellosis], [Rickettsial infections], [Murine Typhus].
- 76. Protect dogs by killing chewing lice that may [vector] [transmit] [carry] tapeworm [infections].
- 77. Protect dogs by repelling biting flies that may cause fly strike [dermatitis].

Long Neck Applicator:

[Note to reviewer: "New" will only be used 6 months from the date EPA is notified of first use]

- 78. New long-neck applicator
- 79. Long-neck makes it easy to get through fur to skin
- 80. New applicator makes it easy to get through long or thick fur and direct to skin

{Optional Icons}











Flea



Fleas

Mosquitoes

Lice

Flea Eggs Larvae

Waterproof