



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs

Registration Division (7505P)

1200 Pennsylvania Ave., N.W.

Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration

☐ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

11556-127

Date of Issuance:

10/10/24

Term of Issuance:

Conditional

Name of Pesticide Product:

Advantage II Large Dog

Name and Address of Registrant (include ZIP Code):

J. Todd Frank
Senior Regulatory Affairs Consultant
Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140

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:

Venus Eagle, Product Manager 01
Invertebrate and Vertebrate Branch 3, Registration Division

Date:

10/10/24

2. Consistent with the guidance on [Pet Spot-On Enhanced Reporting Implementation \(updated Aug. 2019\)](#), the Agency has reviewed your request to remove the two-year registration expiration date and has found your company to be in compliance with the terms and conditions for the subject product. Further, the Agency has reviewed a sample of enhanced reporting using EPA's standardized templates, as described in Condition 3 hereafter, and concluded that the use of the standardized templates for enhanced reporting for this product will considerably improve pharmacovigilance and thus the continued safety of this product. Therefore, the Agency is removing the two-year registration expiration date for this product. The product remains subject to all other previously required conditions of registration, including the submission of enhanced incident reports and sales information as stated in the amendment letter dated 09/18/2007 and amended below to require continued use of the standardized templates.
3. The Agency has reviewed your request to change the terms of your registration from quarterly to annual submission of enhanced incident and sales reports using EPA's standardized templates. Based on an initial screening of sample enhanced reports, the sample submission was determined to be adequate and the templates were successfully used. Therefore, the condition of quarterly submission of enhanced incident and sales reports is hereby amended to annual submission with continued use of these standardized templates. You must submit enhanced incident and sales reports for this product to the Agency every 12 months from the date the product is first released for shipment, or from the end date in the last quarterly enhanced reporting submission. The initial released-for-shipment date must be provided to the Product Manager, once known. The enhanced reporting submission should be addressed to the Product Manager's attention and must use the standardized, electronic templates available on the EPA website through the following links: [Enhanced Incident Reporting Template](#), [Sales Reporting Template](#). Submissions must be received by the Agency no later than 60 days following the completion of the 12-month period. If the product is not marketed or sold, you must submit to the Product Manager a letter to this effect every 12 months in lieu of the enhanced incident and sales reports. Please follow appropriate procedures and flag any Confidential Business Information as such.
4. Submit one copy of the final printed label for the record before you release the product for shipment. This labeling supersedes all previously accepted 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.

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 terms and conditions, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). 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 Loren LaPointe via email at LaPointe.Loren@epa.gov.

Enclosure: stamped label

NOTE TO REVIEWER: Braces “{ }” indicate notes to reviewer. Brackets “[]” indicate optional language.

{Front Panel}

For Use ONLY on Dogs and Puppies
7 Weeks and Older and Weighing 21-55 lbs.

{A large, clear picture of a dog in the appropriate weight range for the product will appear on the front panel.
See page 14.}

Advantage™ II Large Dog

{Alternate Brand Names are listed at the end of this document.}

{The “Large Dog” text size will be 40% - 75% of the height of the largest letter in the primary brand name.}

{Selected optional marketing claims bulleted and pictograms from pages 13-14}

ACTIVE INGREDIENTS:	<u>% by Weight</u>
Imidacloprid.....	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS:	<u>90.44%</u>
TOTAL	100.00%

Once-A-Month Topical Treatment for Fleas and Lice
For Use ONLY on Dogs and Puppies 7 Weeks and Older and Weighing 21-55 lbs.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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

EPA Reg. No. 11556-127 EPA Est. No. XXX
{EPA Reg. No. and EPA Est. No. to appear on front or back panel}

Lot No.

{Lot No. to appear on any panel (front, side, top, or bottom) of outer container}

ACCEPTED

Oct 10, 2024

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 11556-127



DO NOT USE ON CATS

{Icon Size 1.5 cm x 1.5 cm, Background yellow with black text. Positioned in the lower right hand of
package.}

{Back Panel}

Advantage II Large Dog

{The “Large Dog” text size will be 40% - 75% of the height of the largest letter in the primary brand name.}

Once-A-Month Topical Treatment for Fleas and Lice [for Dogs and Puppies]
For Use ONLY on Dogs and Puppies 7 Weeks and Older and Weighing 21-55 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations on Dogs

{Selected optional marketing claims bulleted from pages 13-14}

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.
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. [For medical emergencies call 888-545-5973. For consumer questions call 888-545-5973.] [For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 888-545-5973.] {choice of either or both phone number statements will be used}	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Harmful if on skin. Causes moderate eye irritation. Avoid contact with eyes, skin and clothing. Wash hands after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies or dogs under 7 weeks of age or weighing less than 21 lbs. 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.

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 888-545-5973.

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.

{Icon size 1.5cm x 1.5 cm}



{Do Not Use On Cats box will be located immediately below Side Effects box on back panel. Icon will be yellow with black images & text unless alternate color scheme is justified.}

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

RESTRICTIONS:

- FOR EXTERNAL USE ONLY.
- Use only on dogs seven [7] weeks and older and weighing 21-55 lbs.
- DO NOT use on other animals.
- Weigh your dog before applying to ensure you are applying the correct dose for the weight of your dog.
- DO NOT apply more than one [1] tube per treatment.
- DO NOT have contact or allow children to have contact with treated area until completely dry.
- DO NOT allow your dog to ingest this product.
- In multi-dog households DO NOT allow dogs to have contact with each other until the product has dried.
- DO NOT allow children to apply the product.
- Dogs should be dry prior to application and remain dry for 24 hours after application.

See inside flap for HOW TO OPEN and HOW TO APPLY or insert [leaflet] for full Directions for Use.

Net Contents: 1[2][3][4][5][6][8][10][12] Tube[s] each 0.085 fl. oz. (2.5 mL)
{one of the above Net Content quantities will be used based on the number of tubes in the carton}

[Sample – NOT for Sale]

{Note to reviewer: cartons containing 1 or 2, individually pouched, tubes are completely labeled (all components) as the 3, 4, 5, 6, 8, 10, and 12 tubes. The “Sample – NOT for Sale” is used as text for the 1 or 2 carton only.}

EPA Reg. No. 11556-127 EPA Est. No. XXX

Manufactured For:
Elanco US Inc
2500 Innovation Way
Greenfield, IN 46140
Product of Germany

{Additionally, Inside Flap of Unit Carton for 1, 2, 3, 4, 5, 6, 8, 10 or 12 tubes}

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.
{options of “HOW TO OPEN” and “HOW TO APPLY” will be selected based on packaging}

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.
4. Repeat steps 1 to 3 for each 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.

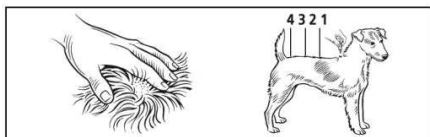
HOW TO APPLY

{OPTION 1: INSTRUCTIONS FOR BLISTER PACK AND SHORT NECK TUBE POUCH}

1. Use only on dogs 7 weeks and older and weighing 21-55 lbs. Do not use on 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 blister [pouch] from the carton. See “HOW TO OPEN” section.
4. Hold tube in an upright position facing away from you and your dog’s face and eyes. Pull cap off tube.



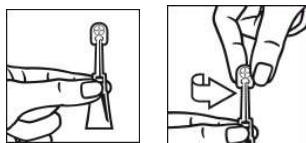
5. Turn the cap around and place other end of cap back on tube.
6. Twist cap to break seal, then remove cap from tube.
7. The dog should be standing for easy application. Apply the entire contents of the tube evenly to three or four spots on the top of the back from the shoulder to the base of the tail. 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. *Do not get this product in your dog’s eyes or allow your dog to ingest this product.*



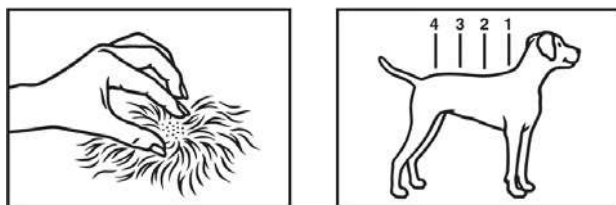
8. Discard empty tube as described in the Storage and Disposal section.
9. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not retreat more often than once every seven (7) days, not to exceed 4 weekly treatments. After flea control is attained, return to a monthly treatment schedule.

[OPTION 2: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

1. Use only on dogs 7 weeks and older and weighing 21-55 lbs. Do not use on 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 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 four (4) 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. Once the infestation is under control, return to a monthly treatment schedule.

{Insert/Leaflet}

Advantage II Large Dog

{The “Large Dog” text size will be 40% - 75% of the height of the largest letter in the primary brand name.}

Once-A-Month Topical Treatment for Fleas and Lice
For Use ONLY on Dogs and Puppies 7 Weeks and Older and Weighing 21-55 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations on Dogs

{Selected optional marketing claims bulleted here from pages 13-14}

ACTIVE INGREDIENTS:	<u>% by Weight</u>
Imidacloprid.....	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS:	90.44%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

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.
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. [For medical emergencies call 888-545-5973. For consumer questions call 888-545-5973.] [For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 888-545-5973.] {choice of either or both phone number statements will be used}	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Harmful if on skin. Causes moderate eye irritation. Avoid contact with eyes, skin and clothing. Wash hands after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies or dogs under 7 weeks of age or weighing less than 21 lbs. 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.

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 888-545-5973.

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.

{Icon size 1.5cm x 1.5 cm}



DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

RESTRICTIONS:

- FOR EXTERNAL USE ONLY
- Use only on dogs seven [7] weeks and older and weighing 21-55 lbs.
- DO NOT use on other animals.
- Weigh your dog before applying to ensure you are applying the correct dose for the weight of your dog.
- DO NOT apply more than one [1] tube per treatment.
- DO NOT have contact or allow children to have contact with treated area until completely dry.
- DO NOT allow your dog to ingest this product.
- In multi-dog households DO NOT allow dogs to have contact with each other until the product has dried.
- DO NOT allow children to apply the product.
- Dogs should be dry prior to application and remain dry for 24 hours after application.

{options of “HOW TO OPEN” and “HOW TO APPLY” will be selected based on packaging}

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.
4. Repeat steps 1 to 3 for each 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.

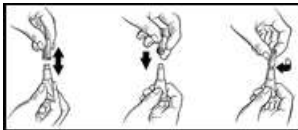
[OPTION 3: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

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.

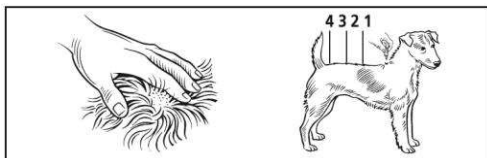
HOW TO APPLY

{OPTION 1: INSTRUCTIONS FOR BLISTER PACK AND SHORT NECK TUBE POUCH}

1. Use only on dogs 7 weeks and older and weighing 21-55 lbs. Do not use on 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 blister [pouch] from the carton. See “HOW TO OPEN” section.
4. Hold tube in an upright position facing away from you and your dog’s face and eyes. Pull cap off tube.



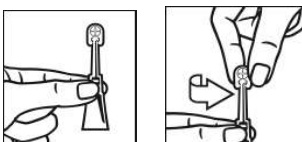
5. Turn the cap around and place other end of cap back on tube.
6. Twist cap to break seal, then remove cap from tube.
7. The dog should be standing for easy application. Apply the entire contents of the tube evenly to three or four spots on the top of the back from the shoulder to the base of the tail. 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. *Do not get this product in your dog’s eyes or allow your dog to ingest this product.*



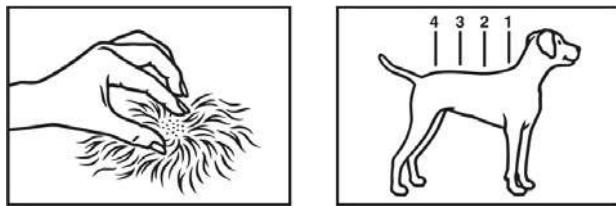
8. Discard empty tube as described in the Storage and Disposal section.
9. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not retreat more often than once every seven (7) days, not to exceed 4 weekly treatments. After flea control is attained, return to a monthly treatment schedule.

[OPTION 2: INSTRUCTIONS FOR LONG NECK TUBE POUCH]

1. Use only on dogs 7 weeks and older and weighing 21-55 lbs. Do not use on 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 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 four (4) 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. Once the infestation is under control, return to a monthly treatment schedule.

PRODUCT INFORMATION

[The successive feeding activity of fleas on dogs frequently elicits a hypersensitivity skin disorder known as flea allergy dermatitis (FAD) or flea bite hypersensitivity. Treatment of dogs with Advantage II Large Dog kills fleas rapidly, within 12 hours, which may reduce the incidence of this condition.]

[Advantage II Large Dog kills existing fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for four (4) weeks.]

[Advantage II Large Dog provides multi-stage flea control effectively breaking flea life-cycle stages.]

Advantage II Large Dog kills adult fleas quickly, within 12 hours, inhibits the development of immature flea life stages and prevents them from reaching the biting adult stage.

Advantage II Large Dog kills [biting/chewing] lice that infest dogs and puppies and prevents further infestations.

Advantage II Large Dog is waterproof 24 hours after application and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

To successfully prevent and control fleas, all dogs must be treated with their own dose of Advantage II Large Dog .

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 Advantage II Large Dog is applied and remains dry 24 hours after application.

Even indoor dogs need protection against fleas because you or other pets in the household may bring fleas 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.

For optimal control and prevention of fleas on dogs, apply monthly.

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. **Pesticide Disposal and Container Handling:** Nonrefillable 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 or 888-545-5973 for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY, DISCLAIMER, AND LIMITATION OF DAMAGES

By using, buying or handling this product, user and/or buyer accepts the following terms. Subject to the inherent risks referred to above, and to the extent consistent with applicable law, Elanco US Inc.'s ("Elanco") sole and exclusive limited warranty is that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label, when used in accordance with the label under normal use conditions. To the extent consistent with applicable law, the above exclusive express limited warranty is void if the product is used contrary to the label. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ELANCO MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ELANCO DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, AND DISCLAIMS ANY OTHER EXPRESS WARRANTY.** No agent of Elanco is authorized to make any other warranty, except in writing with a specific reference to this warranty. ***To the extent consistent with applicable law, Elanco shall not be liable whatsoever for special, incidental or consequential damages resulting from the use or handling of this product. To the extent consistent with applicable law, the sole and exclusive remedy of the user and/or buyer for any and all losses, injuries, or damages, regardless of the legal theory, shall not exceed the purchase price paid for the product, or the replacement of product.*** To the extent the above disclaimer of warranties disclaims implied warranties, it may be limited or ineffective if you are a "consumer" and this product is a "consumer product," as those terms are defined by the Magnuson Moss Act, 15 U.S.C. § 2301, in which case the duration of any implied warranties is limited to the earlier of either the applicable statute of limitation or repose, and in no case will any implied warranty extend beyond the term of the Exclusive Express Limited Warranty for the product. To the extent consistent with applicable law, some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

Manufactured For:
Elanco US Inc
2500 Innovation Way
Greenfield, IN 46140
[Product of Germany]

EPA Reg. No. 11556-127 [EPA Est. No. XXX]

{OPTION 1: Label on blister pack; one blister pack containing 1, 2, 3, 4, 5, 6, 8, 10 or 12 tubes}
{OPTION 2: Label on pouch containing 1 tube}

{Additional label text for one tube sample package: THIS UNIT NOT FOR SALE}

Advantage II Large Dog

For external use only on dogs and puppies 7 weeks and older and weighing 21-55 lbs.

See insert [leaflet] for complete product information.

9.10% Imidacloprid

0.46% Pyriproxyfen

1[2][3][4][5][6][8][10][12] Tube[s] - 0.085 fl. oz. (2.5 mL)

{one of the above quantities will be used based on the number of tubes in carton}

[THIS UNIT NOT FOR SALE]

EPA Reg. No. 11556-127

ELANCO

Lot No.



{Label on Individual Tube - label is colored coded to age and weight grouping}

Advantage II Large Dog

9.10% Imidacloprid
0.46% Pyriproxyfen

0.085 fl. oz. (2.5 mL)

EPA Reg. No. 11556-127

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read The Entire Label Before Use

ELANCO

Lot No.

{Optional marketing claims appearing on any location:}

1. For use on dogs and puppies 7 weeks of age and older and weighing 21-55 lbs.
2. Advantage II [Large Dog] contains imidacloprid and an insect growth regulator
3. Advantage II [Large Dog] contains imidacloprid and pyriproxyfen
4. Advantage II [Large Dog] contains imidacloprid and the insect growth regulator [IGR] pyriproxyfen
5. A single topical application remains effective for 4 weeks [a month]
6. Convenient, easy-to-apply topical solution
7. Convenient, easy-to-apply and fragrance free [monthly] [topical solution]
8. Once a month topical flea treatment for dogs 7 weeks of age and older and weighing 21-55 lbs.
9. Advantage II is for the prevention and treatment of fleas on dogs 7 weeks of age and older and weighing 21-55 lbs.
10. For the treatment and prevention of flea [and lice] infestations on dogs
11. One treatment prevents further flea infestations for 4 weeks [a month]
12. Kills fleas on dogs within [12] hours and continues to prevent infestations for four weeks [a month]
13. Kills fleas on dogs within [12] hours of application
14. Stops existing flea infestations by killing adult fleas
15. Prevents reinfestations by killing adult fleas so they can't lay eggs
16. Prevents flea eggs from hatching [into biting adults]
17. Effectively breaks the flea life cycle
18. Effectively targets life stages of fleas after application
19. Kills [Controls] flea life stages
20. Flea prevention and treatment – kills adult fleas, flea larvae, and flea eggs
21. 3-way protection against fleas kills [controls] adults, larvae, and eggs
22. Prevents [Stops] flea eggs [and flea larvae] from developing into [biting] [adult] fleas
23. Treatment with Advantage II kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
24. Flea adulticide, larvicide, and ovicide
25. Kills flea eggs
26. Works through contact. Fleas do not have to bite your dog to die.
27. Controls flea problems on dogs
28. Protection against fleas
29. Starts working through contact
30. Use flea prevention year-round
31. Contains an insect growth regulator [IGR] to kill flea eggs and prevent re-infestation
32. Monthly use of Advantage II kills fleas which may cause flea allergy dermatitis [flea bite hypersensitivity]
33. Multi-stage flea control
34. Kills fleas which may serve as intermediate hosts for tapeworms
35. Kills [biting/chewing] lice
36. For treatment and prevention of [biting/chewing] lice [infestations]
37. Controls existing [biting/chewing] lice infestations
38. Dual protection against fleas and lice
39. Treats, prevents and controls [biting/chewing] lice [infestations] on dogs
40. Provides effective control of [biting/chewing] lice [infestations] on dogs
41. Kills [biting/chewing] lice and prevents further infestations on dogs
42. For treatment and prevention of infestations with [biting/chewing] lice on dogs
43. Remains effective after bathing and/or swimming
44. Remains effective following swimming and/or shampooing
45. Waterproof after 24 hours
46. Remains effective after exposure to rain or sunlight
47. Fragrance-free

48. In child-resistant packaging
49. Dogs or puppies should be dry prior to application and remain dry for 24 hours after application
[for product to work effectively]
50. Kills fleas, flea eggs, flea larvae and prevents infestations on dogs
51. Prevents re-infestations on dogs
52. Kills fleas and their eggs
53. Protects dogs against fleas
54. Protects dogs against flea infestations
55. Prevents [establishment of] new flea infestations on dogs after application
56. Kills fleas that may cause transmission of tapeworms in dogs
57. Kills fleas which may cause Flea Allergy Dermatitis and flea bite anemia
58. Kills fleas that may cause a tapeworm infestation in dogs
59. Protection from fleas for your dog when applied monthly
60. Kills fleas even if your dog gets wet
61. 1[2][3][4][5][6][8][10][12] monthly doses

Long Neck Applicator:

62. Long-neck applicator
63. Long-neck makes it easy to get through fur to skin
64. Applicator makes it easy to get through long or thick fur and direct to skin

{Optional pictograms which may appear on the label.}

{image of short neck tube, will only appear with instructions for the short neck tube.}



{Alternate Brand Names}

1. Advantage™ II Plus Large Dog*
*Contains imidacloprid and pyriproxyfen
2. Advantage™ II Max Large Dog**
**Contains imidacloprid and pyriproxyfen as compared to Advantage for Large Dogs containing only imidacloprid
3. Advantage™ II Advanced Large Dog
4. Advantage™ II Advanced Care Large Dog
5. Advantage™ II Protect Large Dog

{Representative dog; each outer carton will have a representative picture of a dog in the appropriate age and weight range for the product}

{Representative dog picture optional on insert/leaflet, blister pack, pouch, tube}

