ON THE STATES TO NOT THE PROTECTION OF THE PROTE	U.S. ENVIRONMENTAL PROTECTION AGENCY	EPA Reg. Number:	Date of Issuance:	
TON TON	Office of Pesticide Programs			
MINORIA VAGE	Registration Division (7505P)	11556-152	10/10/24	
TWAL PROTECTION	1200 Pennsylvania Ave., N.W.			
	Washington, D.C. 20460			
NOTICE OF PESTICIDE:		Term of Issuance:		
X Registration				
	Reregistration	Conditional		
	(under FIFRA, as amended)			
, , , , ,		Name of Pesticide Product:		
		Advantage II Lar	ge Cat	
Name and Address of Regis	trant (include ZIP Code):			
J. Todd Frank				
Senior Regulatory	Affairs Consultant			
Elanco US Inc.				
2500 Innovation W	/ay			
Greenfield, IN 461	40			
<b>Note:</b> Changes in labeling d	iffering in substance from that accepted in connection with this re	egistration must be submitted to	and accepted by the	
Registration Division prior to	o use of the label in commerce. In any correspondence on this pr	oduct always refer to the above I	EPA registration number.	
	ormation furnished by the registrant, the ab Insecticide, Fungicide and Rodenticide Act.	ove named pesticide	is hereby registered	
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				

Signature of Approving Official:

Date:

10/10/24

product under FIFRA when the Agency requires all registrants of similar products to submit such

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

data.

- 2. Consistent with the guidance on <a href="Pet Spot-On Enhanced Reporting Implementation">Pet Spot-On Enhanced Reporting Implementation</a> (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. 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, as stated in registration notice dated 06/24/2010 except as amended in paragraph 2 below.
- 3. Please note that the Agency has already 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. Under the conditions of those terms, the sample submission was determined to be adequate, and the templates were successfully used and therefore, the condition of quarterly submission of enhanced incident and sales reports was amended to annual submission with continued use of these standardized templates as stated in Condition 2 of the registration notice dated 9/27/2021.
- 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

Page 3 of 3 EPA Reg. No. 11556-152 Case No. 632020

If you have any questions, please contact Loren LaPointe by phone at 202-560-1230, or via email at <u>LaPointe.Loren@epa.gov</u>.

**Enclosure: Stamped label** 

Date: 08/06/2024 Supersedes: 01/02/2018

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

## **{Front Panel}**

For Use ONLY on Cats and Kittens 8 Weeks and Older and Weighing Over 9 lbs.

{A large, clear picture of a large cat appropriate weight range for the product will appear on the front panel. See page 13.}

## Advantage<sup>TM</sup> II Large Cat

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

{The "Large Cat" 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 12-13}

ACTIVE INGREDIENTS:	% by Weight
Imidacloprid	9.10%
Pyriproxyfen.	0.46%
OTHER INGREDIENTS:	
TOTAL	100.00%

Once-A-Month Topical Flea Prevention and Treatment for Cats and Kittens For Use ONLY on Cats and Kittens 8 Weeks and Older and Weighing Over 9 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. 11556-152 EPA Est. No. XXX {EPA Reg. No. and EPA Est. No. to appear on either 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. 44550 450

11556-152

#### {Back Panel}

## **Advantage II Large Cat**

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

Once-A-Month Topical Flea Prevention and Treatment for Cats and Kittens For Use ONLY on Cats and Kittens 8 Weeks and Older and Weighing Over 9 lbs.

## READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations on Cats and Kittens.

{Selected optional marketing claims bulleted from pages 12-13}

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	Take off contaminated clothing. Rinse skin immediately with plenty of water for		
Clothing:	15 - 20 minutes.		
	Call a poison control center or doctor for treatment advice.		
HOT LINE NUMBER			
Have the product conta	Have the product container or label with you when calling a poison control center or doctor or going for		
treatment. [For medical emergencies or 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 sympt	tomatically.		

## 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 apply to cats or kittens under 8 weeks of age or weighing less than 9 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities may occur after using ANY pesticide product for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

{Side Effects box to go on [lower] right side of back panel.}

**Side Effects:** Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as hypersalivation, 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.

## **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 cats or kittens eight [8] weeks and older and weighing over 9 lbs.
- DO NOT apply to cats or kittens weighing less than 9 lbs.
- DO NOT use on other animals.
- Weigh your cat before applying to ensure you are applying the correct dose for the weight of your cat.
- DO NOT apply more than one [1] tube per treatment, even for larger cats.
- DO NOT have contact or allow children to have contact with treated area until completely dry.
- DO NOT allow your cat to ingest this product.
- In multi-cat households DO NOT allow cats to groom each other until the product has dried.
- DO NOT allow children to apply the product.
- Cats or kittens 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 0.027 fl. oz. (0.8 mL) {one of the above Net Content quantities will be used based on the number of tubes in the carton}

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

[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.}

# {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 cats or kittens 8 weeks and older and weighing over 9 lbs. Do not apply to cats or kittens weighing less than 9 lbs. Do not use on other animals.
- 2. Cats 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 cat'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. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. Do not get this product in your cat's eyes or allow your cat to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.



- 8. Discard empty tube as described in Storage and Disposal.
- 9. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) 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 cats or kittens 8 weeks and older and weighing over 9 lbs. Do not apply to cats or kittens weighing less than 9 lbs. Do not use on other animals.
- 2. Cats or kittens 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 cat's face and eyes. Twist the tip of the applicator to break seal.





5. In order to ensure proper application, part the hair on the neck at the base of the skull. Place the tip of the tube against the cat's skin.





- 6. Gently squeeze the tube to expel the entire contents of the tube directly on the skin.
- 7. Do not get this product in your cat's eyes or allow your cat to ingest this product. Do not allow the product to run off of the cat. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product.
- 8. Discard the empty tube as described in the Storage and Disposal section.
- 9. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. Do not retreat more often 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 Cat

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

Once-A-Month Topical Flea Prevention and Treatment [for Cats] For Use ONLY on Cats and Kittens 8 Weeks and Older and Weighing Over 9 lbs.

#### READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations on Cats

{Selected optional marketing claims bulleted here from pages 12-13}

ACTIVE INGREDIENTS:	<u>% by Weight</u>
Imidacloprid	9.10%
Pyriproxyfen.	0.46%
OTHER INGREDIENTS:	
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	Take off contaminated clothing. Rinse skin immediately with plenty of water for		
Clothing:	15 - 20 minutes.		
_	Call a poison control center or doctor for treatment advice.		
	HOT LINE NUMBER		
Have the product conta	ainer or label with you when calling a poison control center or doctor or going for		
treatment. [For medical	al emergencies or consumer questions call 888-545-5973.] [For product questions, to		
report adverse reaction	s, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary		
Support at 888-545-59	73.] {choice of either or both phone number statements will be used}		
NOTE TO PHYSICIAN			
Treat the patient sympt	comatically.		

## 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 apply to cats or kittens under 8 weeks of age or weighing less than 9 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities may occur after using ANY pesticide product for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

**Side Effects:** Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as hypersalivation, 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.

## **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 cats or kittens eight [8] weeks and older and weighing over 9 lbs.
- DO NOT apply to cats or kittens weighing less than 9 lbs.
- DO NOT use on other animals.
- Weigh your cat before applying to ensure you are applying the correct dose for the weight of your cat.
- DO NOT apply more than one [1] tube per treatment, even for larger cats.
- DO NOT have contact or allow children to have contact with treated area until completely dry.
- DO NOT allow your cat to ingest this product.
- In multi-cat households DO NOT allow cats to groom each other until the product has dried.
- DO NOT allow children to apply the product.
- Cats or kittens 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)**

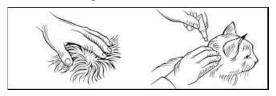
- 1. Use only on cats or kittens 8 weeks and older and weighing over 9 lbs. Do not apply to cats or kittens weighing less than 9 lbs. Do not use on other animals.
- 2. Cats should be dry prior to application and remain dry for 24 hours after application [for product to work effectively].
- 3. Remove one blister [pouch] from the carton. See "HOW TO OPEN" section.
- 4. Hold tube in an upright position facing away from you and your cat'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. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. Do not get this product in your cat's eyes or allow your cat to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.



- 8. Discard empty tube as described in Storage and Disposal.
- 9. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) 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 cats or kittens 8 weeks and older and weighing over 9 lbs. Do not apply to cats or kittens weighing less than 9 lbs. Do not use on other animals.
- 2. Cats or kittens 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 cat's face and eyes. Twist the tip of the applicator to break seal.





5. In order to ensure proper application, part the hair on the cat's neck at the base of the skull. Place the tip of the tube against the cat's skin.





- 6. Gently squeeze the tube to expel the entire contents of the tube directly on the skin.
- 7. Do not get this product in your cat's eyes or allow your cat to ingest this product. Do not allow

- the product to run off of the cat. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product.
- 8. Discard the empty tube as described in the Storage and Disposal section.
- 9. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. Do not retreat more often 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 cats frequently elicits a hypersensitivity skin disorder known as flea allergy dermatitis (FAD) or flea bite hypersensitivity. Treatment of cats with Advantage II Large Cat kills fleas and may reduce the incidence of this condition.]

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

[Advantage II Large Cat provides multi-stage flea control effectively breaking flea life-cycle stages for lasting control (up to four weeks) of flea populations.]

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

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

Apply monthly treatments for optimal control and prevention of fleas.

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

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

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

Remember, your cat needs to be dry at the time Advantage II Large Cat is applied and remains dry 24 hours after application.

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

#### 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. 11556-152 [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)**

## **Advantage II Large Cat**

For external use only on cats and kittens 8 weeks and older and weighing over 9 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] - 0.027 fl. oz. (0.8 mL) {one of the above Net Content quantities will be used based on the number of tubes in the carton}

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

EPA Reg. No. 11556-152

ELANCO Lot No.

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

**Advantage II Large Cat** 

9.10% Imidacloprid 0.46% Pyriproxyfen

0.027 fl. oz. (0.8 mL)

EPA Reg. No. 11556-152

## 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 cats and kittens 8 weeks of age and older and weighing over 9 lbs.
- 2. Advantage II Large Cat contains imidacloprid and an insect growth regulator
- 3. Advantage II Large Cat contains imidacloprid and pyriproxyfen
- 4. Advantage II Large Cat contains imidacloprid and the insect growth regulator [IGR] pyriproxyfen
- 5. A single topical application remains effective for up to 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 prevention and treatment for cats and kittens 8 weeks of age or older and weighing over 9 lbs.
- 9. Advantage II Large Cat is for the prevention and treatment of fleas on cats and kittens 8 weeks of age and older and weighing over 9 lbs.
- 10. For the prevention and treatment of flea infestations on cats
- 11. One treatment prevents further flea infestations for up to 4 weeks [a month]
- 12. Kills fleas within 12 hours on cats and continues to prevent infestations for up to four weeks [a month]
- 13. Kills fleas on cats 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. Reinfesting fleas on cats are killed within 2 hours providing protection against further flea infestation
- 17. Prevents flea eggs from hatching [into biting adults]
- 18. Effectively breaks the flea life cycle
- 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 flea eggs from developing into [biting] [adult] fleas
- 23. Treatment of cats with Advantage II Large Cat kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- 24. Flea adulticide, larvicide, and ovicide
- 25. Kills flea eggs
- 26. Controls flea problems on cats
- 27. Advantage II Large Cat may be used year-round for flea prevention
- 28. Contains an insect growth regulator (IGR) to kill flea eggs and prevent re-infestation
- 29. Monthly use of Advantage II Large Cat on cats kills fleas which may cause [flea allergy dermatitis] [flea bite hypersensitivity]
- 30. Controls existing flea infestations on your cat and prevents further infestations
- 31. Prevents fleas on treated cats from reinfesting
- 32. Remains effective after bathing
- 33. Remains effective following shampooing
- 34. Waterproof, after 24 hours
- 35. Remains effective after exposure to rain or sunlight
- 36. Fragrance-free
- 37. In child-resistant packaging
- 38. Starts working through contact. [Fleas do not have to bite your cat to die.]
- 39. Cats or Kittens should be dry prior to application and remain dry for 24 hours after application [for product to work effectively]
- 40. Kills fleas, flea eggs and flea larvae
- 41. Prevents re-infestations on cats
- 42. Kills fleas and their eggs
- 43. Protects [cats] against fleas

- 44. Protects [cats] against flea infestations
- 45. Prevents [establishment of] new flea infestations on cats after application
- 46. Kills fleas that may cause transmission of tapeworms in cats
- 47. Kills fleas which may cause Flea Allergy Dermatitis and flea bite anemia
- 48. Prevents flea reinfestation [re-infestation] on cats
- 49. Kills fleas that may cause a tapeworm infestation in cats
- 50. Protection from fleas for your cat when applied monthly
- 51. Kills fleas even if your cat gets wet
- 52. 1[2][3][4][5][6][8][10][12] monthly doses

## **{Optional marketing claims for long neck applicator:}**

- 53. Long-neck applicator
- 54. Long-neck makes it easy to get through fur to skin
- 55. 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 the instructions for the short neck tube}











Fleas

{Alternate Brand Names}

- Advantage™ II Plus Large Cat\*
   \*Contains imidacloprid and pyriproxyfen
- 2. Advantage<sup>TM</sup> II Max Large Cat\*\*
  - \*\*Contains imidacloprid and pyriproxyfen as compared to Advantage for Large Cats containing only imidacloprid
- 3. Advantage<sup>TM</sup> II Advanced Large Cat
- 4. Advantage<sup>TM</sup> II Advanced Care Large Cat
- 5. Advantage<sup>TM</sup> II Protect Large Cat

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

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

