

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 24, 2022

Johnna Bridges Sr Advisor, Regulatory Elanco US Inc. 2500 Innovation Way Greenfield, IN 46140

Subject: PRIA Label and CSF Amendment – Addition of Large Cat Use, Change in Primary Brand Name, Addition of Claims, and Other Label Revisions Product Name: Advantage XD Cat EPA Registration Number: 72642-11 Application Date: February 5, 2021; April 29, 2021 Decision Numbers: 571158, 575430

Dear Johnna Bridges:

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

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

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

• Basic CSF dated 02/24/2022

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.

Page 2 of 2 EPA Reg. No. 72642-11 Decision No. 571158, 575430

Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Christopher M. Taylor by phone at 202-566-2928, or via email at <u>taylor.christopher.m@epa.gov</u>.

Sincerely,

Michael Walsh Product Manager 11 Invertebrate & Vertebrate Branch 2 Registration Division Office of Pesticide Programs

Attachment

{NOTE TO REVIEWER: Alternative language in [brackets]; {Braces} indicate Note to Reviewer and will not be included on final label.

The product name Advantage XD Cat is being used as the primary brand name with the product sold under the small cat and large cat alternate brand names.}

CARTON LABEL

FRONT PANEL

Advantage[™] XD Small Cat

{Alternate brand names: Advantage 2M Small Cat; Advantage XX Small Cat; Cheristin Plus Small Cat}

{Note to Reviewer: Size of the words "Small Cat" will be at least 75% the height of the largest letter in the primary brand name.}

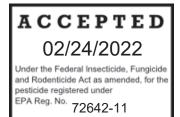
Spinetoram {will appear in close proximity to product name}

AN [EIGHT WEEK] [2 MONTH] TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE AND OLDER AND WEIGHING BETWEEN 1.8 AND 9 [LBS.] [POUNDS]

{Marketing claims: see list at end of the label}

Large, Clear Picture of Cat or Kitten within the Age and Weight Range for the Product



[Image of Tube(s) with # doses icon]

[x Dose[s] = x Months] {Examples: 1 dose = 2 months; 4 Doses = 8 Months}

ACTIVE INGREDIENT

| Spinetoram* | | 15.0% |
|-----------------|-------|--------|
| OTHER INGREDIEM | NTS | 85.0% |
| | TOTAL | 100.0% |

*CAS #s 187166-40-1 and 187166-15-0

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR FIRST AID AND ADDITIONAL PRECAUTIONARY

STATEMENTS READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

[1][one][2][two][3][three][4][four][5][five][6][six][7][seven][8][eight][9][nine][10][ten][11][eleve n][12][twelve] – [0.0338 fl oz] 1 mL applicator[s]

BACK PANEL

DIRECTIONS FOR USE

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

Do not allow children to apply product. Do not allow children to come in contact with the treated cat until after the application has dried. Do not use on cats or kittens less than 8 weeks of age and weighing less than 1.8 [lbs.] [pounds]. Do not double dose cats larger than 9 [lbs.] [pounds]. Do not allow your cat to ingest this product. Cat must be dry at time of application. **Do not apply more than one dose every two months.**

More detailed directions for use, including storage and disposal, are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Application every two months [every other month] is recommended to prevent and treat flea infestations. Advantage[™] XD Small Cat starts working in 30 minutes – 4 hours and kills fleas for [two months] [8 weeks] after application on cats up to 9 [lbs.] [pounds].

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

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

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. As with any product, consult your veterinarian before using the product on medicated, debilitated, aged, pregnant or nursing cats or cats known to be sensitive to pesticides. In multiple cat households, do not allow the cats to groom each other until the product has dried.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

{Note to Reviewer: The "Side Effects" box will be located at the lower right-hand corner of the back panel.}

FIRST AID

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a 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.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

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

EPA Reg. No. 72642-11 EPA Est. No.

PACKAGE INSERT LABEL

Advantage[™] XD Small Cat

{Note to Reviewer: Size of the words "Small Cat" will be at least 75% the height of the largest letter in the primary brand name.}

Spinetoram

AN [EIGHT WEEK] [2 MONTH] TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE AND OLDER AND WEIGHING 1.8 [LBS] [POUNDS] TO [-] 9 LBS [POUNDS]

ACTIVE INGREDIENT

| Spinetoram* | | 15.0% |
|-------------------|-------|--------|
| OTHER INGREDIENTS | | 85.0% |
| | TOTAL | 100.0% |

*CAS #s 187166-40-1 and 187166-15-0

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

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

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. As with any product, consult your veterinarian before using the product on medicated, debilitated, aged, pregnant or nursing cats or cats known to be sensitive to pesticides. In multiple cat households, do not allow the cats to groom each other until the product has dried.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a 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.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

DIRECTIONS FOR USE:

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

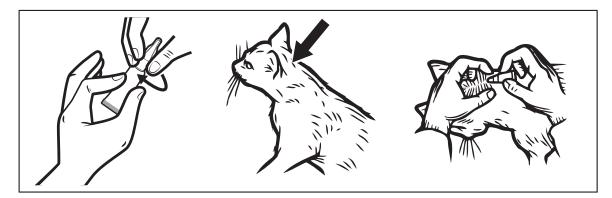
Read the entire label, directions for use and frequency of application each time before using the product. Do not allow children to apply product. Do not allow children to come in contact with the treated cat until after the application has dried. Do not use on cats or kittens less than 8 weeks of age and weighing less than 1.8 [lbs.] [pounds]. Do not double dose cats larger than 9 [lbs.] [pounds]. Do not allow your cat to ingest this product. Cat must be dry at time of application. **Do not apply more than one dose every two months.**

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply one applicator tube, every two months [every other month], only to cats and kittens 8 weeks of age and older and weighing between 1.8 [lbs.] [pounds] and 9 [lbs.] [pounds].

HOW TO APPLY {Twist Open Applicator}

- 1. Remove one applicator tube from the tray.
- 2. Hold applicator tube in an upright position.
- 3. Open applicator tube by twisting the nozzle tip.
- 4. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between shoulder blades. Avoid getting the product in your cat's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product.
- 5. Discard empty applicator tube in the trash.



Application every two months [every other month] is recommended to prevent and treat flea infestations. Advantage[™] XD Small Cat starts working in 30 minutes – 4 hours and continues killing fleas for [two full months] [eight full weeks] after application.

STORAGE AND DISPOSAL

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

Pesticide Storage:

Store in original package in a cool dry place inaccessible to children and animals.

Pesticide Disposal:

Call your local solid waste agency or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

<u>If empty</u>: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

<u>If partly filled:</u> Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

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

EPA Reg. No. 72642-11 EPA Est. No.

Applicator Labeling

Advantage[™] XD Small Cat

Spinetoram 15%

Only for cats & kittens 8 weeks & older [weighing] between 1.8 - 9 lbs.

[0.0338 fl oz] 1 mL

EPA Reg No 72642-11

CAUTION Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

[TWIST TO OPEN]

[Lot No] xxx

CARTON LABEL

FRONT PANEL

Advantage[™] XD Large Cat

{Alternate brand names: Advantage 2M Large Cat; Advantage XX Large Cat; Cheristin Plus Large Cat}

{Note to Reviewer: Size of the words "Large Cat" will be at least 75% the height of the largest letter in the primary brand name.}

Spinetoram {will appear in close proximity to product name}

AN [EIGHT WEEK] [2 MONTH] TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE AND OLDER AND WEIGHING [MORE THAN] [>] 9 [LBS.] [POUNDS]

{Marketing claims: see list at end of the label}

Large, Clear Picture of Cat or Kitten within the Age and Weight Range for the Product

[Image of Tube(s) with # of doses icon]

[x Dose[s] = x Months] {Examples: 1 dose = 2 months; 4 Doses = 8 Months}

ACTIVE INGREDIENT

| Spinetoram* | | 15.0% |
|-------------------|-------|-------|
| OTHER INGREDIENTS | | |
| | TOTAL | |
| | | |

*CAS #s 187166-40-1 and 187166-15-0

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR FIRST AID AND ADDITIONAL PRECAUTIONARY

STATEMENTS READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

BACK PANEL

DIRECTIONS FOR USE

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

Do not allow children to apply product. Do not allow children to come in contact with the treated cat until after the application has dried. Do not use on cats or kittens less than 8 weeks of age and weighing less than 9 [lbs.] [pounds]. Do not double dose cats larger than 9 [lbs.] [pounds]. Do not allow your cat to ingest this product. Cat must be dry at time of application. **Do not apply more than one dose every two months.**

More detailed directions for use, including storage and disposal, are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Application every two months [every other month] is recommended to prevent and treat flea infestations. Advantage[™] XD Large Cat starts working in 30 minutes – 4 hours and kills fleas for [two months] [8 weeks] after application on cats more than 9 [lbs.] [pounds].

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

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

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. As with any product, consult your veterinarian before using the product on medicated, debilitated, aged, pregnant or nursing cats or cats known to be sensitive to pesticides. In multiple cat households, do not allow the cats to groom each other until the product has dried.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

{Note to Reviewer: The "Side Effects" box will be located at the lower right-hand corner of the back panel.}

FIRST AID

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a 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.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

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

EPA Reg. No. 72642-11 EPA Est. No.

PACKAGE INSERT LABEL

Advantage[™] XD Large Cat

{Note to Reviewer: Size of the words "Large Cat" will be at least 75% the height of the largest letter in the primary brand name.}

Spinetoram

AN [EIGHT WEEK] [2 MONTH] TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE AND OLDER AND WEIGHING [MORE THAN] [>] 9 LBS [POUNDS]

| ACTIVE INGREDIENT | | |
|-------------------|-------|--------|
| Spinetoram* | | 15.0% |
| OTHER INGREDIENTS | | 85.0% |
| | TOTAL | 100.0% |

*CAS #s 187166-40-1 and 187166-15-0

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

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

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. As with any product, consult your veterinarian before using the product on medicated, debilitated, aged, pregnant or nursing cats or cats known to be sensitive to pesticides. In multiple cat households, do not allow the cats to groom each other until the product has dried.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a 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.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

DIRECTIONS FOR USE:

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

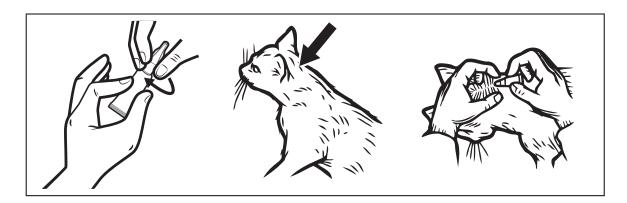
Read the entire label, directions for use and frequency of application each time before using the product. Do not allow children to apply product. Do not allow children to come in contact with the treated cat until after the application has dried. Do not use on cats or kittens less than 8 weeks of age and weighing less than 9 [lbs.] [pounds]. Do not double dose cats larger than 9 [lbs.] [pounds]. Do not allow your cat to ingest this product. Cat must be dry at time of application. **Do not apply more than one dose every two months.**

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply one applicator tube, every two months [every other month], only to cats and kittens 8 weeks of age and older and weighing [more than] [>] 9 [lbs.] [pounds].

HOW TO APPLY {Twist Open Applicator}

- 1. Remove one applicator tube from the tray.
- 2. Hold applicator tube in an upright position.
- 3. Open applicator tube by twisting the nozzle tip.
- 4. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between shoulder blades. Avoid getting the product in your cat's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product.
- 5. Discard empty applicator tube in the trash.



Application every two months [every other month] is recommended to prevent and treat flea infestations. Advantage[™] XD Large Cat starts working in 30 minutes – 4 hours and continues killing fleas for [two full months] [eight full weeks] after application.

STORAGE AND DISPOSAL

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

Pesticide Storage:

Store in original package in a cool dry place inaccessible to children and animals.

Pesticide Disposal:

Call your local solid waste agency or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

<u>If empty</u>: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

<u>If partly filled:</u> Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES. EXPRESSED OR IMPLIED. OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

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

EPA Reg. No. 72642-11 EPA Est. No.

Applicator Labeling

Advantage[™] XD Large Cat

Spinetoram 15%

Only for cats & kittens 8 weeks & [weighing] > 9 lbs.

[0.067 fl oz] 2 mL

EPA Reg No 72642-11

CAUTION Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

[TWIST TO OPEN]

[Lot No] xxx

Optional Marketing Claims for Small and Large Cat

- 1. Every [two] [2] months
- 2. Every 8 weeks
- 3. Every other month
- 4. Topical
- 5. Topical Solution
- 6. Single topical [spot-on] application
- {Small Cat:} For the prevention and treatment of flea infestations [*Ctenocephalides felis*] and only for use on cats [and kittens] 8 weeks of age or older and weighing 1.8 [lbs.] [pounds] to 9 [lbs.] [pounds]
- {Large Cat:} For the prevention and treatment of flea infestations [*Ctenocephalides felis*] and only for use on cats [and kittens] 8 weeks of age or older and weighing [more than] [>] 9 [lbs.] [pounds]
- 9. Kills fleas for [8 weeks] [2 months]
- 10. Prevents [fleas] [re]infestations
- 11. [Fast Acting] kills fleas on cats within 8 hours
- 12. [Fast Acting] starts killing fleas [in] [within] 30 minutes 4 hours
- 13. [Fast Acting] starts working [in] [within] 30 minutes 4 hours
- 14. Kills fleas which may cause flea allergy dermatitis [FAD]
- 15. [Long Lasting] one treatment prevents further flea infestations for 8 weeks [2 months]
- 16. [Long Lasting] one treatment remains effective for 8 weeks [2 months]

{Page 16 of 18}

- 17. [Long Lasting] remains effective for 8 weeks [2 months]
- 18. Fragrance-free
- 19. {Small Cat:} Formulated only for cats and kittens 8 weeks of age and older and weighing 1.8 [lbs.] [pounds] to [-] 9 [lbs.] [pounds]
- 20. {Large Cat:} Formulated only for cats and kittens 8 weeks of age and older and weighing [more than] [>] 9 [lbs.] [pounds]
- 21. Kills fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*, *Francisella tularensis*
- 22. Kills fleas that may carry and transmit bartonellosis, tapeworm and tularemia
- 23. For indoor and outdoor cats and kittens
- 24. Long-lasting flea control [through] [for] [8 weeks] [2 months]
- 25. The primary target of action of spinetoram on insects is an activation of nicotinic acetylcholine receptors [nAChRs].
- 26. Spinetoram does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes.
- 27. Insects in contact with spinetoram show involuntary muscle contractions and tremors resulting from activation of motor neurons.
- 28. Prolonged spinetoram-induced hyperexcitation results in prostration and paralysis resulting in death of fleas.
- 29. Topical application
- 30. {Small Cat:} One dose [(1 mL)] size for cats and kittens 8 weeks of age and older and weighing 1.8 [lbs.] [pounds] to 9 [lbs.] [pounds].
- 31. {Large Cat:} One dose [(2 mL)] size for cats and kittens 8 weeks of age and older and weighing [more than] [>] 9 [lbs.] [pounds].
- 32. {Small Cat:} One [applicator tube] [1 mL] [size] [package] [dose] [treatment] [application] treats cats and kittens 8 weeks of age and older and weighing 1.8 [lbs.] [pounds] to 9 [lbs.] [pounds].
- 33. {Large Cat:} One [applicator tube] [2 mL] [size] [package] [dose] [treatment] [application] treats cats and kittens 8 weeks of age and older and weighing [more than] [>] 9 [lbs.] [pounds].
- 34. [1] [one] [2] [two] [3] [three] [4] [four] [5] [five] [6] [six] [7] [seven] [8] [eight] [9] [nine] [10] [ten] [11] [eleven] [12] [twelve] [applications] [applicator tubes] [individual doses] [topical applicators]
- 35. Single Pack [Single dose] [Individual dose]
- 36. Topical flea treatment
- 37. Topical flea infestation prevention
- 38. Flea treatment & prevention [icon]
- 39. Convenient
- 40. Easy to apply [Easy to use]
- 41. Spinetoram, the active ingredient in Advantage[™] XD [Small] [Large] Cat, is a member of the spinosyn class of pesticides.
- 42. {Small Cat:} Protects cats and kittens 8 weeks of age and older and weighing between 1.8 [lbs.] [pounds] to 9 [lbs.] [pounds] from fleas for [8 weeks] [two months].
- 43. {Large Cat:} Protects cats and kittens 8 weeks of age and older and weighing [more than] [>] 9 [lbs.] [pounds] from fleas for [8 weeks] [two months].
- 44. {Small Cat:} One [size] application is effective for cats and kittens 8 weeks of age and older and weighing 1.8 [lbs.] [pounds] to 9 [lbs.] [pounds].

- 45. {Large Cat:} One [size] application is effective for cats and kittens 8 weeks of age and older and weighing [more than] [>] 9 [lbs.] [pounds].
- 46. [Flea infestations may vary] [treatment][application][administration] every two months [every other month] [every 8 weeks] [year-round] is recommended for optimal control and prevention of flea infestations.
- 47. Kills fleas through contact [icon] {The aforementioned text will always appear in close proximity to this icon for clarity on its meaning}
- 48. [Advantage XD] Extended Duration[*] [*]each dose lasts [[two] [2] months] [[8] [eight] weeks] [icon] {* statement will appear in close proximity to 'Extended Duration' claim}
- 49. Kills fleas through contact so fleas don't have to bite [a][your] cat to die.
- 50. [2 Month][8 Week] Topical Flea [Treatment][Prevention][Protection]
- 51. [x Dose[s] = x Months] {Examples: 1 dose = 2 months; 4 Doses = 8 Months; graphic will appear in close proximity to Extended Duration icon on packaging}
- 52. Apply 1 time for 2 months of flea protection
- 53. Apply 1x for 2 months of flea protection
- 54. Apply once for 2 months of flea protection
- 55. 2 month cat flea [protection][prevention][treatment]
- 56. [2][Two] months flea protection, [1][one] easy application
- 57. [2][Two] months of flea protection
- 58. [2][Two] months of flea protection in [a single][1][one] application

Optional Icons



{Extended Duration icon; Each dose lasts 2 months"}



{Flea treatment/ prevention icon}

Kills fleas [thru] through contact {The aforementioned text will always appear in close proximity to this icon for clarity on its meaning}



{Tube image/# doses example; graphic will appear in close proximity to Extended Duration icon on packaging}