



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

EPA Reg. Number:

88052-8

Date of Issuance:

9/12/17

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 9/12/2019

Name of Pesticide Product:

C712.0 FOR DOGS

Name and Address of Registrant (include ZIP Code):

Ann M. Tillman
Horizon Valley Generics, Inc.
c/o Pyxis Regulatory Consulting Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/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:

Elizabeth Fertich, Acting Product Manager 03
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)

Date:

9/12/17

2. The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is extending the two-year registration restriction. This registration is time-limited and expires 9/12/2019.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in the initial registration notice dated 12/13/2012.
4. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Fipronil GDCI-129121-1305
 - b. Fipronil GDCI-129121-1512

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

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

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

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

- Basic CSF dated 06/19/2013

If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Enclosure

09/12/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 88052-8

{FRONT PANEL OF CARTON}

[Optional text appears in brackets – the final label may include some or all of the optional text on front, back, or side label panels or label insert]

{text in {} denotes location of text on packaging, notes to reviewer, text that will not be on final label}

C712.0 FOR DOGS

{The word Dogs in the brand name will be at least 75% the height of the largest letter in the brand name.}

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

{Optional Marketing Claims} [Fleas, Ticks, Chewing Lice]

[Distributor name]

Use only on dogs weighing [5-22 lbs.] [23-44 lbs.] [45-88 lbs.] [89-132 lbs.] and 8 weeks or older [For small dogs and puppies] [For medium dogs] [For large dogs] [for extra-large dogs]

EPA Reg. No. 88052-8

EPA Est. No. 74720-DEU-01

ACTIVE INGREDIENT:

Fipronil 9.7%

OTHER INGREDIENTS: 90.3%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See insert for Precautionary and First Aid Statements and complete Directions for Use

NET CONTENTS: [0.069 fl. oz.] [0.135 fl. oz.] [0.273 fl. oz.] [0.408 fl oz.]

{One of the Net Contents appropriate for the package will appear on final carton}

[Three (3) 0.023 fl. oz. [0.67 mL] applicators]

[Three (3) 0.045 fl. oz. [1.34 mL] applicators]

[Three (3) 0.091 fl. oz. [2.68 mL] applicators]

[Three (3) 0.136 fl. oz. [4.02 mL] applicators]

[CAT PROHIBITION ICON]



{There will be a 1.5cm x 1.5cm cat prohibition icon in a box located at the lower right hand corner of the front panel in yellow with black images.}

{END FRONT PANEL OF CARTON}

{BACK PANEL OF CARTON}

C712.0 FOR DOGS 8 weeks or older weighing [5-22 lbs.] [23-44 lbs.] [45-88 lbs.] [89-132 lbs.]

C712.0 FOR DOGS contains the active ingredient fipronil that effectively kills and controls fleas, ticks, and chewing lice. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in fast-acting, long-lasting activity.

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.** To prevent injury to you and your dog, read entire label and directions on the package insert before each use. Follow all directions and precautionary statements carefully. This product must only be used on dogs. Do not use on rabbits or on other animals. Do not apply to dogs under 8 weeks of age or weighing less than [5] [23] [45] [89] lbs.

[Precaucion al consumidor: Si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

RESTRICTIONS

- Do not use on Cats, rabbits, or other animals.
- Do not use on dogs or puppies under 8 weeks of age or weighing less than [5] [23] [45] [89] lbs.
- Do not allow your dog to ingest product.
- Do not apply more than once every month.
- Do not apply more than one applicator per treatment for one dog regardless of the dog's weight.
- Do not bathe or allow your dog to swim for 24 hours after application.

To kill fleas and all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (which may carry Lyme disease) and chewing lice, apply this product to dogs and puppies 8 weeks or older weighing [5-22][23-44][45-88][89-132] lbs as follows.

To remove and open applicator: See label insert for opening instructions.

INSTRUCTIONS FOR APPLYING PRODUCT

To apply C712.0 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the dog's skin. Your dog needs to be dry at the time of application and remain dry for 24 hours after application. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Do not apply more than one applicator per dog per treatment regardless of the dog's weight.

OR [Alternate application method]

For dogs & puppies 8 weeks and older weighing 5-22 [23-44] [45-88] [89-132] lbs. Apply one applicator from the back of the neck to a point midway between the neck and tail. Allow area to dry before touching treated area. Do not apply more than one applicator per dog per treatment regardless of the dog's weight.

OR [Alternate application method]

For dogs & puppies 8 weeks and older weighing 5-22 [23-44] [45-88] [89-132] lbs. Apply one applicator starting at the base of the tail moving in a straight line toward head against the hair along the backbone (spine). Allow area to dry before touching treated area. Do not apply more than one applicator per dog per treatment regardless of the dog's weight.

C712.0 for Dogs can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant, and lactating bitches. C712.0 for Dogs aids in the control of sarcoptic mange mite infestations. Multiple monthly treatments are recommended for the elimination of mites.


FREQUENCY OF APPLICATION

When used monthly, C712.0 for Dogs completely controls flea, tick, and chewing lice infestations. Research demonstrates that C712.0 for Dogs kills adult fleas for up to three months. Although C712.0 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 for Dogs kills all life stages of ticks (larvae, nymph, and adult) for at least one month. A once monthly application is recommended where tick control is needed. A once monthly application is recommended where chewing lice are present. Applied once a month, C712.0 for Dogs aids in the control of sarcoptic mange mite infestations. C712.0 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. Do not reapply C712.0 for Dogs for 30 days.

Side Effects. Monitor your dog after application. Side effects may include 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 occur, consult your veterinarian or the ASPCA Animal Poison Control Center at 1-888-426-4435.

{A box labeled "Side Effects" will be located immediately above the cat warning box on the back panel.}

{CAT PROHIBITION ICON}


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.

{There will be a 1.5cm x 1.5cm cat prohibition icon and warning text in a box located at the lower right hand corner of the back panel in yellow with black images and text.}

Manufactured for:

[Horizon Valley Generics, Inc.
8735 Rosehill Road
Lenexa, KS 66215]

[MADE IN Germany]

[C712.0 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.]
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{END BACK PANEL OF CARTON}

{SIDE PANELS}

[C712.0] FOR DOGS & PUPPIES

Use only on dogs weighing [5-22 lbs.][23-44 lbs.][45-88 lbs.][89-132 lbs.] and 8 weeks or older

[For small dogs and puppies] [For medium dogs] [For large dogs] [for extra-large dogs]

{PACKAGE INSERT}

C712.0 FOR DOGS 8 weeks or older weighing [5-22][23-44][45-88][89-132] lbs.

EPA Reg. No. 88052-8

[EPA Est. No. 74720-DEU-01]

ACTIVE INGREDIENT:

Fipronil 9.7%

OTHER INGREDIENTS: 90.3%

TOTAL: 100.0%

Kills fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease) and chewing lice

KEEP OUT OF REACH OF CHILDREN

CAUTION

C712.0 for Dogs contains the active ingredient fipronil that effectively kills and controls fleas, ticks, and chewing lice. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

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.** To prevent injury to you and your dog, read entire label and directions on the package insert before each use. Follow all directions and precautionary statements carefully. This product must only be used on dogs. Do not use on rabbits or on other animals. Do not apply to dogs weighing less than [5] [23] [45] [89] lbs.

Precaucion al consumidor: Si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).

RESTRICTIONS

- Do not use on Cats, rabbits, or other animals.
- Do not use on dogs or puppies under 8 weeks of age or weighing less than [5] [23] [45] [89] lbs.
- Do not allow your dog to ingest product.
- Do not apply more than once every month.
- Do not apply more than one applicator per treatment for one dog regardless of the dog's weight.
- Do not bathe or allow your dog to swim for 24 hours after application.

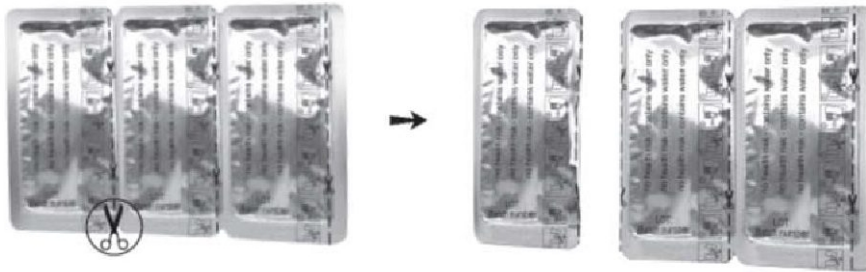
To kill fleas and all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (which may carry Lyme disease) and chewing lice, apply this product to dogs and puppies (8 weeks or older) as follows.

To remove and open applicator:

[To remove and open applicator, see reverse side.]

{ILLUSTRATIONS FOR OPENING PRODUCT}

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



{ILLUSTRATIONS FOR APPLYING PRODUCT}



To apply C712.0 for Dogs: Place applicator tip through dog's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the dog's skin. Your dog needs to be dry at the time of application and remain dry for 24 hours after application. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Do not apply more than one applicator per dog per treatment regardless of the dog's weight.

OR [Alternate application method]

For dogs & puppies 8 weeks and older weighing 5-22 [23-44] [45-88] [89-132] lbs. Apply one applicator from the back of the neck to a point midway between the neck and tail. Allow area to dry before touching treated area. Do not apply more than one applicator per dog per treatment regardless of the dog's weight.

OR [Alternate application method]

For dogs & puppies 8 weeks and older weighing 5-22 [23-44] [45-88] [89-132] lbs. Apply one applicator starting at the base of the tail moving in a straight line toward head against the hair

along the backbone (spine). Allow area to dry before touching treated area. Do not apply more than one applicator per dog per treatment regardless of the dog's weight.

C712.0 for Dogs can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant, and lactating bitches. C712.0 for Dogs aids in the control of sarcoptic mange mite infestations. Multiple monthly treatments are recommended for the elimination of mites.

FREQUENCY OF APPLICATION

When used monthly, C712.0 FOR DOGS completely controls flea, tick, and chewing lice infestations. Research demonstrates that C712.0 FOR DOGS kills adult fleas for up to three months. Although C712.0 FOR DOGS can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 FOR DOGS kills all stages of ticks (larvae, nymph, and adult) for at least one month. A once monthly application is recommended where tick control is needed. A once monthly application is recommended where chewing lice are present. Applied once a month, C712.0 for Dogs aids in the control of sarcoptic mange mite infestations. C712.0 FOR DOGS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply C712.0 FOR DOGS for 30 days.

{CAT PROHIBITION ICON}



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.

Side Effects. Monitor your dog after application. Side effects may include 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 occur, consult your veterinarian or the ASPCA Animal Poison Control Center at 1-888-426-4435.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • 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 a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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.
HOTLINE NUMBER:	
<p>Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact the ASPCA Animal Poison Control Center at 1-888-426-4435 for emergency medical treatment information.</p>	

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS**

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

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age. Do not use on dogs or puppies weighing less than [5] [23] [45] [89] lbs. Individual sensitivities, while rare, may occur after using any pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call the ASPCA Animal Poison Control Center at 1-888-426-4435 for assistance.

[QUESTIONS [OR COMMENTS] ABOUT THIS PRODUCT]

Call the ASPCA Animal Poison Control Center at 1-888-426-4435

[GRAPHICS/PICTURES of Appropriate size dog]

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

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

Pesticide Storage. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. Nonrefillable container. Do not reuse or refill this container. If partly filled, call your local solid waste agency [or 1-800-CLEANUP] for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.

HOW SUPPLIED

C712.0 FOR DOGS is available in convenient sizes for small dogs and puppies 8 weeks or older and 5-22 lbs., medium dogs 23-44 lbs., large dogs 45-88 lbs., and extra-large dogs 89-132 lbs.

5-22 lbs.	Contains 3 - 0.023 fl. oz. (0.67 mL) applicators
23-44 lbs.	Contains 3 - 0.045 fl. oz. (1.34 mL) applicators
45-88 lbs.	Contains 3 - 0.091 fl. oz. (2.68 mL) applicators
89-132 lbs.	Contains 3 - 0.136 fl. oz. (4.02 mL) applicators

WARRANTY

To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this

product. Seller shall return the purchase price or at the election of the seller replace the product.

Manufactured for:

[Horizon Valley Generics, Inc.
8735 Rosehill Road
Lenexa, KS 66215]

[MADE IN Germany]

[C712.0 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.]

[©20xx Horizon Valley Generics, Inc. All rights reserved.]

{Text for Back of Blister Pack}

{Pictogram with scissors and cut-line (see CRP opening instructions photo above)}

Keep Out of Reach of Children

Read entire label including carton and insert before use.

For external use only

CAUTION

Cat prohibition icon



DO NOT USE ON CATS

**Use ONLY on Dogs [5-22] [23-44] [45-88] [89-132] lbs and 8 weeks or older
[0.023] [0.045] [0.091] [0.136] fl. oz.**

C712.0 for Dogs

Fipronil 9.7%

EPA Reg. No. 88052-8

Lot No.

{Text for Back of Applicator}

Keep Out of Reach of Children

Read entire label including carton and insert before use.

For external use only

CAUTION

DO NOT USE ON CATS

C712.0 for Dogs

Fipronil 9.7%

EPA Reg. No. 88052-8

Lot No.

**Use ONLY on Dogs [5-22] [23-44] [45-88] [89-132] lbs and 8 weeks or older
[0.023] [0.045] [0.091] [0.136] fl. oz.**

[Care card/reminder stickers]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply C712.0 for Cats to your cat.]

[Remove the adhesive backing and attach to your refrigerator [door].]

[Reminder]

[Care Card]

[Reminder sticker for Month 1, Date of Application]
[Reminder sticker for Month 2], Date of Application
[Reminder sticker for Month 3, Date of Application]
[Dog's name; lbs.]

{OPTIONAL MARKETING CLAIMS}

1. [Fast-acting, long-lasting, convenient spot treatment for control of fleas, ticks and chewing lice]
2. [Waterproof]
3. **[C712.0 FOR DOGS** provides convenient and effective flea, tick, and chewing lice control for dogs and puppies.]
4. [Fast acting and long-lasting]
5. [Prevents re-infestation of fleas]
6. [Convenient to use]
7. [Kills (newly emerged) adult fleas before they lay eggs]
8. [Controls adult fleas which may cause flea allergy dermatitis [FAD]]
9. [Kills all stages of brown dog ticks [(*R. sanguineus*)], American dog ticks [(*D. variabilis*)], lone star ticks [(*Amblyomma americanum*)], and deer ticks [(*Ixodes scapularis*)] [which may carry Lyme disease]]
10. Kills Fleas, [Chewing] Lice]
11. [Controls infestations with chewing lice]
12. [Controls chewing lice infestations]
13. [Aids in control of sarcoptic mange mite infestations]
14. [Can be used on breeding, pregnant and lactating bitches]
15. [Waterproof (water resistant)]
16. [Kills adult fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia)]
17. [Protects [your dog] from fleas, ticks, chewing lice and mosquitoes for one month]
18. [Effective monthly treatment of fleas, ticks and lice]
19. [Remains effective after bathing and swimming]
20. [Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, and anaplasmosis]
21. [(Easy,) (fast,)(effective) control of fleas, ticks and lice]
22. [Kills fleas [ticks] [lice] [chewing lice] [mites]]
23. [Kills adult fleas that may cause flea bite anemia]
24. [Optional graphics: Picture of Flea]
25. [Optional graphics: Picture of tick]
26. [Optional graphics: Picture of louse]
27. [Contains the active ingredient fipronil]
28. [Convenient to use]
29. [Long lasting]
30. [Fast acting]
31. [Controls infestations with chewing lice]
32. [Controls infestation and prevents re-infestation of fleas]
33. [Kills all stages of deer ticks]
34. [Prevents infestations of adult fleas and adult ticks.]
35. [Apply monthly]
36. [Controls mites that may cause sarcoptic mange]
37. [Best results when used monthly (year round)]
38. [Apply monthly for year-round protection from fleas, ticks, chewing lice and mosquitoes]
39. [Kills newly emerged fleas before they lay eggs]
40. [Calendar stickers inside]
41. [3 Doses [Inside]]
42. [Contains] [3 Month Supply]
43. [Contains] [3 Applicators]
44. [9.7% Fipronil]
45. [Fipronil 9.7%]
46. [Controls flea re-infestation for up to one month (4 weeks)]
47. [pictogram of [applicator(s)]]