



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

EPA Reg. Number:

88052-9

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 CATS

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:

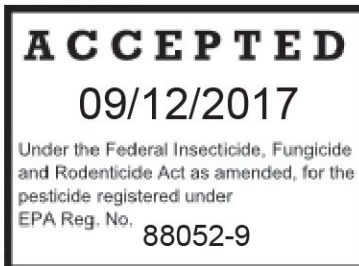
- Basic CSF dated 06/19/2013

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

[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}

{FRONT PANEL OF CARTON}



**C712.0 FOR CATS
8 WEEKS AND OLDER AND 1.5 LBS OR GREATER**

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

DO NOT USE ON DOGS

{Optional Marketing Claims}

Use only on cats and kittens 8 weeks or older and 1.5 lbs or greater

[distributor name]

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

EPA Reg. No. 88052-9

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: 0.051 fl. oz.

Three (3) 0.017 fl. oz. [0.50 mL] applicators

{END FRONT PANEL OF CARTON}

{BACK PANEL OF CARTON}

C712.0 FOR CATS 8 WEEKS AND OLDER AND 1.5 LBS OR GREATER

C712.0 FOR CATS 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 cat, 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 cats. Do not use on dogs, rabbits or on other animals. Do not use on cats or kittens under 8 weeks of age or on kittens weighing less than 1.5 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 dogs, rabbits or other animals.
- Do not use on cats or kittens under 8 weeks of age or on kittens weighing less than 1.5 lbs.
- Do not allow your cat to ingest product.
- Do not apply more than once every month.
- Do not apply more than one applicator per treatment for one cat regardless of the cat's weight.
- Do not bathe or allow your cat to swim for 24 hours after application.
- In multi-cat households do not allow cats to groom each other until product has dried.

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 cats and kittens (8 weeks or older and weighing 1.5 lb. or greater) as follows.

INSTRUCTIONS FOR APPLYING PRODUCT

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

To apply C712.0 FOR CATS: Place applicator tip through cat's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the cat's skin. Your cat needs to be dry at the time of application and remain dry for 24 hours after application. Avoid superficial application to the cat's hair. Allow area to dry before touching treated area. Separate treated cat from all other cats and pets until product has dried. Use one applicator per treatment per month.

[ILLUSTRATIONS FOR APPLYING PRODUCT]

C712.0 FOR CATS can also be used for the treatment and control of flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

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

{A box labeled "Side Effects" will be located in the lower right hand corner of the back panel.}

Side Effects. Monitor your cat 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.

Manufactured for:

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

[MADE IN GERMANY]

[C712.0 FOR CATS/ trade name is a registered trademark of Horizon Valley Generics, Inc.]
[©2015 Horizon Valley Generics, Inc. All rights reserved.]

{SIDE PANELS}

[C712.0] FOR CATS]

Use only on cats and kittens 8 weeks or older and 1.5 lbs or greater

{PACKAGE INSERT}

**C712.0 FOR CATS
8 WEEKS AND OLDER AND 1.5 LBS OR GREATER**

EPA Reg. No. 88052-9

[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 CATS 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 cat, 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 cats. Do not use on dogs, rabbits or on other animals. Do not use on cats or kittens under 8 weeks of age or on kittens weighing less than 1.5 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

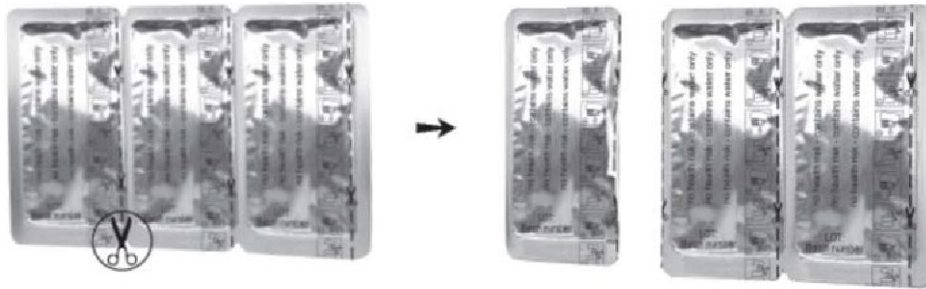
- Do not use on dogs, rabbits or other animals.
- Do not use on cats or kittens under 8 weeks of age or less than 1.5 lbs.
- Do not allow your cat to ingest product.
- Do not apply more than once every month.
- Do not apply more than one applicator per treatment for one cat regardless of the cat's weight.
- Do not bathe or allow your cat to swim for 24 hours after application.
- In multi-cat households do not allow cats to groom each other until product has dried

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 cats and kittens (8 weeks or older weighing 1.5 lbs or greater) 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 CATS: Place applicator tip through cat's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the cat's skin. Your cat needs to be dry at the time of application and remain dry for 24 hours after application. Avoid superficial application to the cat's hair. Allow area to dry before touching treated area. Separate treated cat from all other cats and pets until product has dried. Do not apply more than one applicator per cat per treatment regardless of the cat's weight.

C712.0 FOR CATS can also be used for the treatment and control of flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, C712.0 FOR CATS controls flea, tick and chewing lice infestations. Research demonstrates that C712.0 FOR CATS kills adult fleas for up to six weeks. Although

C712.0 FOR CATS can control fleas for up to six weeks, if there is a high risk of re-infestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 FOR CATS kills all stages of ticks (larvae, nymph, and adults) for at least one month. A once monthly application is recommended where tick control is needed. C712.0 FOR CATS kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed. C712.0 FOR CATS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply C712.0 FOR CATS for 30 days.

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 kittens under 8 weeks of age or weighing under 1.5 lb. Do not use on dogs. Individual sensitivities, while rare, may occur after using any pesticide product. Cats 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 immediately. If your cat 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 cats. Call the ASPCA Animal Poison Control Center at 1-888-426-4435 for assistance.

Side Effects. Monitor your cat 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.

[QUESTIONS [OR COMMENTS] ABOUT THIS PRODUCT]
Call the ASPCA Animal Poison Control Center at 1-888-426-4435

[GRAPHICS/PICTURES of cat]

[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

For easy and convenient treatment, C712.0 FOR CATS is available in one convenient size.

Contains 3 - 0.017 fl. oz. (0.50 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 CATS/ 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.

CAUTION

For external use only

Only for Cats & Kittens 8 weeks or older and 1.5 lbs or greater

C712.0 for Cats

Fipronil 9.7%

EPA Reg. No. 88052-9

Lot No.

0.017 fl. oz.

{Text for Back of Applicator}

Keep Out of Reach of Children

Read entire label including carton and insert before use.

CAUTION

For external use only

Only for Cats & Kittens 8 weeks or older and 1.5 lbs or greater

C712.0 for Cats

Fipronil 9.7%

EPA Reg. No. 88052-9

Lot No.

0.017 fl. oz.

[Optional advertising claims: 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]

[Cat'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 CATS provides convenient and effective flea, tick and chewing lice control for cats and kittens.]
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], Fleas, [Chewing] Lice]
10. [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]]
11. [Controls infestations with chewing lice]
12. [Can be used on breeding, pregnant and lactating queens]
13. [Waterproof (water resistant)]
14. [Kills adult fleas that may cause flea allergy dermatitis and flea bite anemia]
15. [Protects [your cat] from fleas, ticks, chewing lice and mosquitoes for one month]
16. [Effective monthly treatment of fleas, ticks and lice]
17. [Remains effective after bathing and swimming]
18. [Kills ticks that may transmit Lyme disease, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, and anaplasmosis]
19. [Easy, fast, effective control of fleas, ticks and lice]
20. [Kills fleas [ticks] [lice] [chewing lice]]
21. [Kills fleas that may cause flea bite anemia]
22. [Optional graphics: Picture of Flea]
23. [Optional graphics: Picture of tick]
24. [Optional graphics: Picture of chewing lice]
25. [Contains the active ingredient fipronil]
26. [Convenient to use]
27. [Long lasting]
28. [Fast acting]
29. [Controls infestations with chewing lice]
30. [Kills all stages of deer ticks]
31. [Best results when used monthly (year round)]
32. [Apply monthly for year round protection from fleas, ticks, chewing lice and mosquitoes]
33. [Kills newly emerged fleas before they lay eggs]
34. [Calendar stickers inside]
35. [Prevents re-infestation of adult fleas and ticks for one month]
36. [3 Doses Inside]
37. [Contains] [3 Month Supply]
38. [Contains] [3 Applicators]
39. [9.7% Fipronil]
40. [Fipronil 9.7%]
41. [pictogram of applicator(s)]
42. [Formulated for cats and kittens 8 weeks and older and 1.5 lb. or greater]