

ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7504P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460-0001 EPA Registration No.

88052-14

Date of Issuance:

April 19, 2013

NOTICE OF PESTICIDE:

☑ Registration

☐ Reregistration

(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product: C710.0 FOR CATS

Name and Address of Registrant (include ZIP Code):

Horizon Valley Generics, Inc.

clo Plyxis Regulatory Consulting, Inc.

4110 136th Street NW

Gig Harbor, WA 98332-9122

ted by the Registration Division prior to use of the label in commerce. In any correspondence on this product 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 heilth 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 lo be construed as giving the registrant a right to exclusive use of the name of to its use if it has been covered by others

This action is taken under the authority of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

Terms of Registration

- EPA has registered the product listed above provided that the following changes are made to the label before you release the product for shipment:
 - Revise the EPA Registration Number to read: "EPA Registration No 88052-14."
- This registration is time-limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.
- 3. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).
- You must submit the following data within the timeframe described below: Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).

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Refer to Page #3

Date:

Richard J. Gebken, Product Manager (10)

Registration Division, Insecticide Branch

April 19, 2013

EPA Form 8570-6

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5. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on July 1, 2013. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division (attn: Katlin Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number

Product name (brand name)

Lot#

Where purchased: internet, store, Veterinarian

Active Ingredient(s)

Weight range for product

Date on which incident occurred, (mm/dd/yyyy)

State in which the incident occurred, (standard 2 letter abbreviation)

Registrant case #

Species: dog, cat, other (specify)

Breed: (as reported by pet owner)

Age: months or years Sex: M, F, or neutered

Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other

Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted

Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor Outcome: died, recovered, still treated, unknown

- 6. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - All minor dermal and ocular irritation reports.
 - Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for cats and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - A summary table for s showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 2 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - f. A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label.
 - g. A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in dogs in upper half of weight range, and cats weighing more than the product weight range.
 - n. Table showing number of incidents for each cat breed.
 - Table showing number of incidents in cat for each clinical sign.
 - Table showing number of incidents in cat for each organ system.
 - Report aggregate incidents, but do not combine moderate and minor incidents.

7. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.

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8. Horizon Valley Generics, Inc. must adequately address all of the mitigation actions identified in the Agency's Generic Pet Spot-On Mitigation Plan available at the following internet site: http://www.epa.gov/pesticides/health/spot-on-meetings.html.

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact Mr. Richard J. Gebken at (703) 305-6701 or gebken richard@epa.gov.

Sincerely,

Richard Gebken

Product Manager 10

Insecticide Branch

Registration Division (7504P)

Enclosure: 5470254

Label Stamped "Accepted with Comments," dated April 19, 2013

(Label Directions for Container (Carton), Package Insert, Blister, and Reminder Stickers for 3 x 0.017 fl. oz. package)

(FRONT PANEL OF CARTON)

C710.0 FOR CATS

Use ONLY on cats weighing over 1.5 lbs. and 8 weeks or older [picture of cat 8-weeks or older]]

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes Kills all stages of Ticks, including those that may transmit Lyme disease

DO NOT USE ON DOGS

[Optional text appears in brackets - the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see lists at the end of the label]

ACTIVE INGREDIENTS:

Fipronil	9.8%
(S)-Methoprene	11.8%
OTHER INGREDIENTS:	78.4%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for FIRST AID and PRECAUTIONARY STATEMENTS

NET CONTENTS:

0.051 fl. oz. (1.5 mL) (3 applicators each containing 0.017 fl. oz. (0.50 mL)); 3 Doses

EPA Reg. No. 88052-RU

EPA Est. 74720-DEU-01

Manufactured for:

Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, Missouri 64106

MADE IN GERMANY

Cino. FOR CATS/ trade name is a registered trademark of Horizon Valley Generics, Inc. ©2012 Horizon Valley Generics, Inc. All rights reserved.

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[WEBSITE]

[Product Bar Code]

ACCEPTED
With COMMENTS
In EPA Letter Dated:

Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

C#10.0 FOR CATS - 4-19-2013 - 88052-RU

88052-14

(BACK PANEL OF CARTON)

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid was agency 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.

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 HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON DOGS, RABBITS OR OTHER ANIMALS.

SIDE EFFECTS

See package insert for side effects.

[Piecaucion 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.)]

C710.0 FOR CATS

C?10:0 FOR CATS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C710.0 is fast-acting, long-lasting, waterproof, and easy to use.

C710:0 FOR CATS remains effective even after bathing, water immersion, or exposure to sunlight. C710:0 FOR CATS can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant and lactating queens.

Do not allow your cat to ingest this product. Do not apply to cats weighing less than 1.5 lbs. and less than 8 weeks old.

To kill fleas, flea eggs, and all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks, chewing lice and mosquitoes, apply this product **ONLY** to cats and kittens weighing over 1.5 lbs. and 8 weeks or older as follows.

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

To apply C710.0 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 on the cat's skin. Avoid superficial application to the cat's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

[PICTOGRAM ON HOW TO APPLY]

(BACK PANEL OF CARTON).

FREQUENCY OF APPLICATION

Fleas: When used monthly, C710.0 FOR CATS kills all stages of the flea life cycle and prevents reinfestation for up to six weeks after application. Although C710.0 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, apply C710.0 FOR CATS once every 30 days.

Ticks: C710.0 FOR CATS kills all stages of the tick life cycle (larvae, nymph, and adult) for at least 30 days. For best control of ticks, apply once every 30 days.

Chewing Lice: C710.0 FOR CATS kills chewing lice for at least 30 days. For best control of chewing lice, apply once every 30 days.

Mosquitoes: Apply C710.0 for Cats every 30 days to kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C710.0 for Cats for 30 days.

(SIDE PANEL OF CARTON)

For use only on Cats & Kittens weighing over 1.5 lbs. and 8 weeks or older Ci 10.0 for Cats [EPA Reg. No. 88052-RU] Lot/Batch Number

[Optional Marketing Claims for Carton and Package Insert]

- [Kills [Fleas], [Flea Eggs] and [Larvae], [Ticks], [Chewing Lice], [Mosquitoes]]
- [Fast-acting, long-lasting, convenient spot treatment for control of [fleas], [ticks], [mosquitoes], and [chewing lice]]
- [C710.0 FOR CATS provides convenient and effective [flea], [tick], [mosquitoes], and [chewing lice] control for cats and [kittens weighing 1.5 lbs and 8 weeks and older]]
- [Fast acting and long lasting]
- [Convenient to use]
- [Prevents [flea eggs], [larvae] and [pupae]from developing
- [Kills [flea eggs], [flea larvae] and [flea pupae]]
- [Controls adult fleas which may cause [FAD] [flea allergy dermatitis]]
- [Kills all stages of Brown Dog ticks (*R. sanguineus*), American dog ticks (*D. variabilis*), Lone Star ticks (*Amblyomma americanum*), [Deer ticks (*Ixodes scapularis*) which may transmit Lyme disease]]
- [Kills tick [nymphs] and [adults]]
- [Rapidly controls infestations with chewing lice]
- [Can be used on [breeding], [pregnant] and [lactating] queens]
- [Waterproof [water resistant]]
- [Kills adult fleas that may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
- [Effective monthly treatment of [fleas], [ticks] and [lice]]
- [Remains effective after [bathing] and [swimming]]
- [Kills ticks that may transmit [Lyme disease], [haemobartonellosis], [ehrlichiosis], [babesiosis], [anaplasmosis]]
- [Easy, fast, effective control of [fleas], [ticks] and [lice]]
- [Kills fleas [ticks] [lice]]
- [Kills mosquitoes]
- [Kills fleas that may cause flea bite anemia]
- [Optional graphics: Picture of Flea]
- [Optional graphics: Picture of tick]
- [Optional graphics: Picture of chewing lice]
- [Contains the same active ingredients fipronil and (S)-methoprene found in Frontline[®]
 Plus]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- [Controls infestations with chewing lice]
- [Kills all stages of deer ticks]
- [Best results when used monthly [year round]]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- [Prevents re-infestation for one month]
- [3 Doses Inside]
- [Contains the same active ingredients fipronil and (S)-methoprene found in Frontline[®]
 Plus]
- [C710.0 FOR CATS is not manufactured by or distributed by Merial]
- [[Especially] [specifically] [expressly] formulated for cats and kittens [weighing over 1.5 lbs. and 8 weeks and older] [only]]
- [C710.0 FOR CATS is not manufactured by or distributed by Merial Limited.]
- [Frontline is a registered trademark of Merial Limited.]
- [Compare to Frontline[®] Plus for Cats]

C710.0 FOR CATS

Use ONLY on cats weighing over 1.5 lbs. and 8 weeks or older [picture of cat]

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes Kills all stages of Ticks, including those that may transmit Lyme disease

DO NOT USE ON DOGS

ACTIVE INGREDIENTS:	
Fibronil	9.8%
(S)-Methoprene	11.8
OTHER INGREDIENTS:	
TÖTAL:	100.0%

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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

HÖTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact us at xxx-xxx for emergency medical treatment information.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on cats only. Do <u>not</u> use on kittens weighing less than 1.5 lbs. and less than 8 weeks of age. DO NOT USE ON DOGS. DO NOT USE ON OTHER ANIMALS. 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. 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 1-xxx-xxx-xxxx for 24-hour assistance.

SIDE EFFECTS

Monitor your cat after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. In some cases, vomiting or diarrhea may result due to grooming after treatment. If these or other side effects occur, consult your veterinarian or call us at xxx-xxx-xxxx.

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 HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS FOR USE BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

Précaucion 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.)

C710.0 FOR CATS

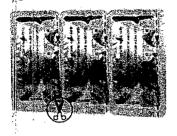
C710.0 FOR CATS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C710.0 is fast-acting, long-lasting, waterproof, and easy to use. C710.0 FOR CATS remains effective even after bathing, water immersion, or exposure to sunlight. C710.0 FOR CATS can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant and lactating queens.

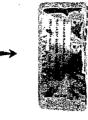
Do not allow your cat to ingest this product. Do not apply to cats weighing less than 1.5 lbs. and less than 8 weeks old.

To kill fleas, flea eggs and larvae, all stages of **Brown Dog ticks**, **American dog ticks**, **Lone Star ticks**, and **Deer ticks** (which may carry Lyme disease), mosquitoes, and chewing lice, apply this product to cats and kittens weighing over 1.5 lbs. and 8 weeks or older as follows.

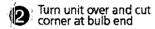
To remove and open applicator:

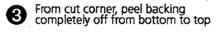
Cut along scissor cut line to separate unit

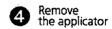


















III.LUSTRATIONS FOR APPLYING PRODUCTI

To apply C710.0 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. Avoid superficial application to the cat's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

FREQUENCY OF APPLICATION

Fleas: When used monthly, C710.0 FOR CATS kills all stages of the flea life cycle and prevents reinfestation for up to six weeks after application. Although C710.0 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, apply C710.0 FOR CATS once every 30 days.

Ticks: C710.0 FOR CATS kills all stages of the tick life cycle (larvae, nymph, and adult) for at least 30 days. For best control of ticks, apply once every 30 days.

Chewing Lice: C710.0 FOR CATS kills chewing lice for at least 30 days. For best control of chewing lice, apply once every 30 days.

Mosquitoes: Apply C710.0 for Cats every 30 days to kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C710.0 FOR CATS for 30 days.

EPA Reg. No. 88052-RU

[EPA Est. 74720-DEU-01]

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT Call xxx-xxx-xxxx
[PRODUCT BAR CODE]
[Website]

STORAGE AND DISPOSAL

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

PLISTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency 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, C710.0 FOR CATS is available in one convenient size.

0.051 fl. oz. (1.5 mL) (3 applicators each containing 0.017 fl. oz. (0.50 mL); 3 Doses

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:

Herizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, Missouri 64106

MADE IN GERMANY

C7/10.0 FOR CATS/ trade name is a registered trademark of Horizon Valley Generics, Inc.

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(Text for CRP Blister)

TOP OF LIDDING FOIL—see back of blister on next page: Detted line with representation of a pair of scissors and two step directions to separate blisters

KEEP OUT OF REACH OF CHILDREN

CAUTION. See full label for additional instructions

C#10.0 for Cats

EPA Reg. No. 88052-RU

Lot/Batch No.

0.017 fl. oz. (0.5 mL) – Only for Cats & Kittens weighing over 1.5 lbs. and 8 weeks or older

Fipronil 9.8%

(S)-Methoprene 11.8%

PIPETTE FOIL

KEEP OUT OF REACH OF CHILDREN

CAUTION.

Read directions before use.

C710.0 for Cats

EPA Reg. No. 88052-RU

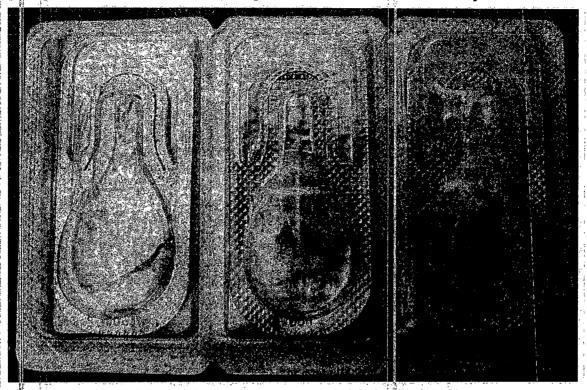
Lot/Batch No.

0.017 fl. oz. (0.5 mL) – Only for Cats & Kittens weighing over 1.5 lbs. and 8 weeks or older

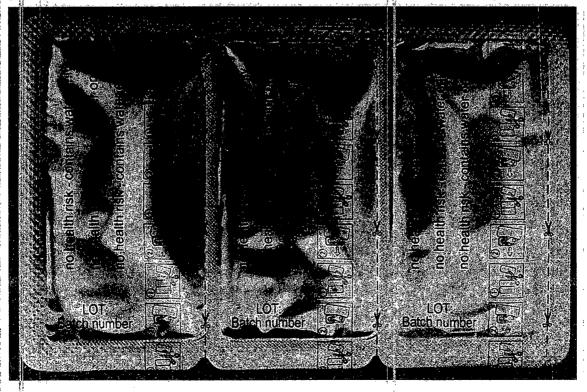
Fipronil 9.8%

(S)-Methoprene 11.8%

[Pictogram of Front of Blister With Opening Instructions - NOT PART OF LABEL]



[Pictogram of Back of Blister With Opening Instructions - NOT PART OF LABEL]



(Text for Reminder Stickers for 3 x 0.017 fl. oz. Package)

[Optional marketing claims]

[Picture of Cat or Kitten (8 weeks or older)]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Optional Bar Code]

C/10.0 for Cats

The first time you treat your cat, place the First Application Sticker on your calendar. Apply Stickers 2 and 3 to the calendar 30 and 60 days after the first application to remind you it's time to reapply C110.0 for Cats.

First Application Sticker: Apply C710.0 for Cats

Month 1 Sticker: Apply C710.0 for Cats

Month 2 Sticker: Apply C710.0 for Cats

For Customer Service please call 1-xxx-xxx-xxxx.

[For more information, visit www.xxxxx.com]

Horizon Valley Generics, Inc. 1201 Walnut Street, Suite 2900 Kansas City, Missouri 64106

[Optional bar code]