

88052-13

9/22/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

SEP 22 2014

Ms. Ann M. Tillman  
Horizon Valley Generics  
c/o Pyxis Regulatory Consulting  
4110 136<sup>th</sup> Street, NW  
Gig Harbor, WA 98332

Subject: Label Notification per PRN 98-10 – Alternate Brand Names  
Product Name: C668.2 for Dogs  
EPA Registration Number: 88052-13  
Application Date: August 21, 2014  
Decision Number: 494977

Dear Ms. Tillman:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand names: Springline® for Dogs and Springline® Spot-On for Dogs has been added to the product record.

If you have any questions, you may contact Melody Banks on 703 305 5413 or E-mail at [banks.melody@epa.gov](mailto:banks.melody@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard Gebken  
Product Manager  
Insecticide Branch  
Registration Division (7504P)

**Label Directions and Container (Carton), Package Insert, Blister, and Reminder Stickers for**

- 3 x 0.023 FL. OZ. PACKAGE**
- 3 x 0.045 FL. OZ. PACKAGE**
- 3 x 0.091 FL. OZ. PACKAGE**
- 3 x 0.136 FL. OZ. PACKAGE**

**(FRONT PANEL OF CARTON)**

**C668.2 FOR DOGS**

**[ALTERNATE BRAND NAMES: Springline® for Dogs, Springline® Spot-On for Dogs]**

(Use **ONLY** on dogs and puppies weighing 6-22 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older; picture of dog in weight class)

(Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks or older; picture of dog in weight class)

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes  
 Kills all stages of Ticks, including those that may transmit Lyme disease  
 Aids in control of sarcoptic mange mite infestations.

[Optional text appears in bracket- 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]

**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.

**ACTIVE INGREDIENTS:**

Fipronil .....	9.8%
(S)-Methoprene .....	8.8

**OTHER INGREDIENTS:** ..... 81.4%

**TOTAL:** ..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See label insert for **FIRST AID** and **PRECAUTIONARY STATEMENTS**

**NET CONTENTS:**

- (0.069 fl. oz. (2.01 mL) (3 applicators each containing 0.023 fl. oz. (0.67 mL); 3 Doses))
- (0.135 fl. oz. (4.02 mL) (3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 Doses))
- (0.273 fl. oz. (8.04 mL) (3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 Doses))
- (0.408 fl. oz. (12.06 mL) (3 applicators each containing 0.136 fl. oz. (4.02 mL); 3 Doses))

EPA Reg. No. 88052-13

EPA Est. 74720-DEU-01

**Manufactured for:**  
 Horizon Valley Generics, Inc.  
 1201 Walnut Street, Suite 2900  
 Kansas City, Missouri 64106

MADE IN Germany  
 C668.2 FOR DOGS/ 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]

### (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 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.

#### 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 DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

#### SIDE EFFECTS

See package insert for side effects.

[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).]

#### C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively kills and controls fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use.

C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 6 pounds.

To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.

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

To apply C668.2 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 on the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

[PICTOGRAM ON HOW TO APPLY]

**FREQUENCY OF APPLICATION**

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 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, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

**(SIDE PANELS OF CARTON)**

- (Use **ONLY** on dogs and puppies 6-22 lbs. and 8 weeks or older)
- (Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)
- (Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)
- (Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 8 weeks)
- [C668.2 for Dogs]
- [EPA Reg. No. 88052-13]
- Lot/Batch Number

[Optional Marketing Claims for Carton and Package Insert]

[Fleas, Ticks, Chewing Lice]

- [[Fast-acting], [long-lasting], [waterproof], [convenient] spot treatment for control of [fleas], [flea eggs] & [flea larvae], [ticks], [mosquitoes], and [chewing lice]]
- [Kills ticks that may transmit Lyme disease]
- [Waterproof]
- [C668.2 FOR DOGS provides [convenient] and [effective] [flea], [tick], [chewing lice], and [mosquito] control for [dogs] and [puppies]]
- [[Fast acting] and [long-lasting]]
- [Waterproof]
- [Convenient to use]
- [Kills [fleas], [flea eggs] and [flea larvae]]
- [Prevents all flea stages [eggs, larvae, pupae] from developing]
- [Controls fleas which may cause [flea allergy dermatitis] [FAD]]
- [Kills all stages of ticks [larva, nymph, and adult]: Brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Lone Star ticks (*Amblyomma americanum*), [Deer ticks (*Ixodes scapularis*) which may carry Lyme disease]]
- [Rapidly controls infestations of chewing lice]
- [Kills mosquitoes]
- [Aids in control of sarcoptic mange mite infestations]
- [Can be used on [breeding], [pregnant] and [lactating] bitches]
- [Waterproof [water resistant]]
- [Kills fleas that may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
- [Effective monthly treatment of [fleas], [ticks], [lice] and [mosquitoes]]
- [Remains effective after [bathing] and [swimming]]
- [Kills ticks that may transmit [Lyme disease], [Rocky Mountain spotted fever], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis]]
- [[Easy], [fast], [effective] control of [fleas], [ticks], [lice] and [mosquitoes]]
- [Kills [fleas], [ticks], [lice]]
- [Kills fleas that may cause flea bite anemia]
- [Optional graphics: Picture of Adult Fleas]
- [Optional graphics: Picture of Flea Eggs]
- [Optional graphics: Picture of Flea Larvae]
- [Optional graphics: Picture of Tick]
- [Optional graphics: Picture of Louse]
- [Optional graphics: Picture of Mosquito]
- [Contains the 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 mosquitoes]
- [Kills all stages of deer ticks]
- [Apply monthly]
- [Aids in the control of sarcoptic mange mites]
- [Best results when used monthly [year round]]
- [For year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- [3 Doses]
- [Controls flea re-infestation for up to three months]

- [C668.2 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [Frontline® Plus is a registered trademark of Merial Limited.]
- [Contains Fipronil and (S)-Methoprene [the same active ingredients used in Frontline® Plus for Dogs]]
- [Compare to Frontline® Plus for Dogs]
- [Contains the same active ingredients as Frontline® Plus for Dogs]
- [C668.2 FOR DOGS is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial.]

7/13

### LABEL DIRECTIONS FOR PACKAGE INSERT

### C668.2 FOR DOGS

[ALTERNATE BRAND NAMES: Springline® for Dogs, Springline® Spot-On for Dogs]

- (Use **ONLY** on dogs and puppies weighing 6-22 lbs. and 8 weeks or older)
- (Use **ONLY** on dogs and puppies weighing 23-44 lbs. and 8 weeks or older)
- (Use **ONLY** on dogs and puppies weighing 45-88 lbs. and 8 weeks or older)
- (Use **ONLY** on dogs and puppies weighing 89-132 lbs. and 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  
 Aids in control of sarcoptic mange mite infestations.

**ACTIVE INGREDIENTS:**

Fipronil .....	9.8%
(S)-Methoprene.....	8.8
<b>OTHER INGREDIENTS:</b> .....	<b>81.4%</b>
<b>TOTAL:</b>	<b>100.0%</b>

**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.

**HOTLINE 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-xxxx 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 only. **FOR USE ON DOGS AND PUPPIES ONLY.** Do not use on puppies under 6 pounds or on puppies under 8 weeks of age. **DO NOT USE ON CATS OR OTHER ANIMALS.** Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian. 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 1-xxx-xxx-xxxx for 24-hour assistance.

## LABEL DIRECTIONS FOR PACKAGE INSERT

### 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 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 DOG, READ THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

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).

### C668.2 FOR DOGS

C668.2 FOR DOGS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C668.2 FOR DOGS is fast-acting, long-lasting, waterproof, and easy to use. C668.2 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. C668.2 for Dogs can also be used on breeding, pregnant, and lactating bitches.

Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 6 pounds.

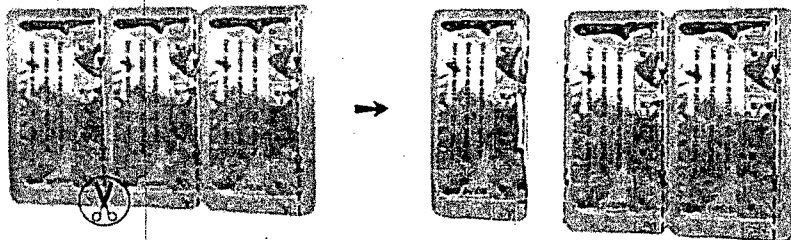
To kill adult fleas, flea eggs and larva, chewing lice, mosquitoes, all stages of **Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks** (which may carry Lyme disease), and to aid in control of sarcoptic mange mites, apply this product **ONLY** to dogs and puppies (8 weeks or older) as follows.



### LABEL DIRECTIONS FOR PACKAGE INSERT

To remove and open applicator:

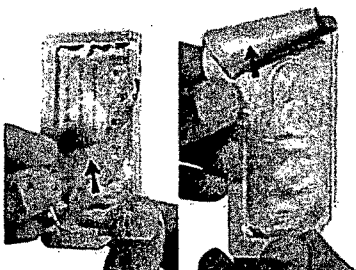
- 1 Cut along scissor cut line to separate unit



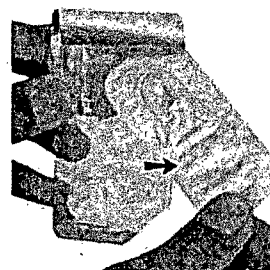
- 2 Turn unit over and cut corner at bulb end



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



- 4 Remove the applicator



#### [PICTOGRAM ON HOW TO APPLY]

To apply C668.2 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. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

#### FREQUENCY OF APPLICATION

Fleas: When used monthly, C668.2 for Dogs breaks the flea life cycle and controls fleas, flea eggs, and flea larvae for up to three months. Although C668.2 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, apply this product once a month.

Ticks: C668.2 for Dogs kills larva, nymph and adult ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, and anaplasmosis for at least one month. For best control of ticks, apply once every month.

Chewing Lice: C668.2 for Dogs kills chewing lice for at least one month. For best control of chewing lice, apply once every month.

Sarcoptic Mites: Applied once a month, C668.2 for Dogs aids in the control of sarcoptic mange mite infestations.

Mosquitoes: A once a month application of C668.2 for Dogs will kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C668.2 for Dogs for 30 days.

### LABEL DIRECTIONS FOR PACKAGE INSERT

#### 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.

EPA Reg. No. 88052-13

[EPA Est. 74720-DEU-01]

#### QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[Website]

[PRODUCT BAR CODE]

#### 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 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

C668.2 FOR DOGS is available in convenient sizes for all sized dogs 6 to 132 lbs.

6-22 lbs.	0.069 fl. oz. (2.01 mL), 3 applicators each containing 0.023 fl. oz. (0.67 mL), 3 doses
23-44 lbs.	0.135 fl. oz. (4.02 mL), 3 applicators each containing 0.045 fl. oz. (1.34 mL); 3 doses
45-88 lbs.	0.273 fl. oz. (8.04 mL), 3 applicators each containing 0.091 fl. oz. (2.68 mL); 3 doses
89-132 lbs.	0.408 fl. oz. (12.06 mL), 3 applicators each containing 0.136 fl. oz. (4.02 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:

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

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.  
©2012 Horizon Valley Generics, Inc. All rights reserved.

**Text for CRP Blister and Pipette**

**TOP OF LIDDING FOIL—see back of blister on next page: Dotted 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**

**C668.2 for Dogs**

**EPA Reg. No. 88052-13**

**Lot/Batch No.**

**CAT PROHIBITION ICON**

- 0.023 fl. oz.** - Only for Dogs & Puppies 6-22 lbs. and 8 weeks or older
- 0.045 fl. oz.** - Only for Dogs & Puppies 23-44 lbs. and 8 weeks or older
- 0.091 fl. oz.** Only for Dogs & Puppies 45-88 lbs. and 8 weeks or older
- 0.136 fl. oz.** Only for Dogs & Puppies weighing 89-132 lbs. and 8 weeks or older

**Fipronil 9.8%**  
**(S)-Methoprene 8.8%**

**PIPETTE FOIL**

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION.**

**Read directions before use.**

**C668.2 for Dogs**

**EPA Reg. No. 88052-13**

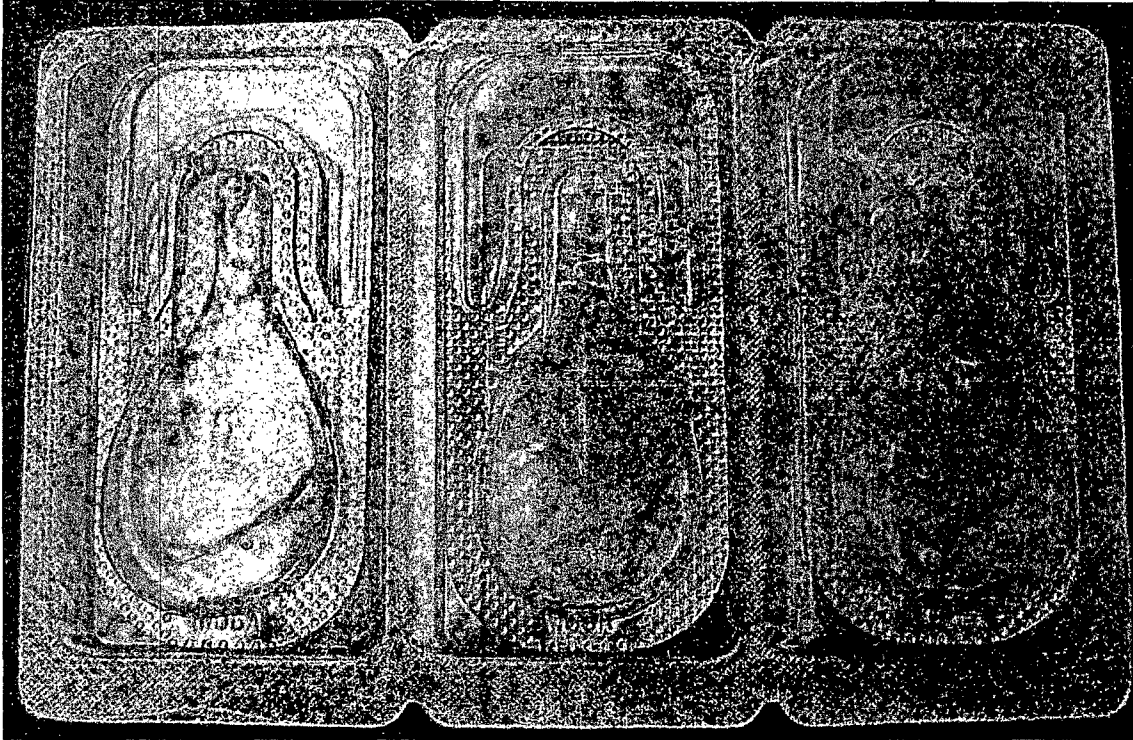
**Lot/Batch No.**

**DO NOT USE ON CATS**

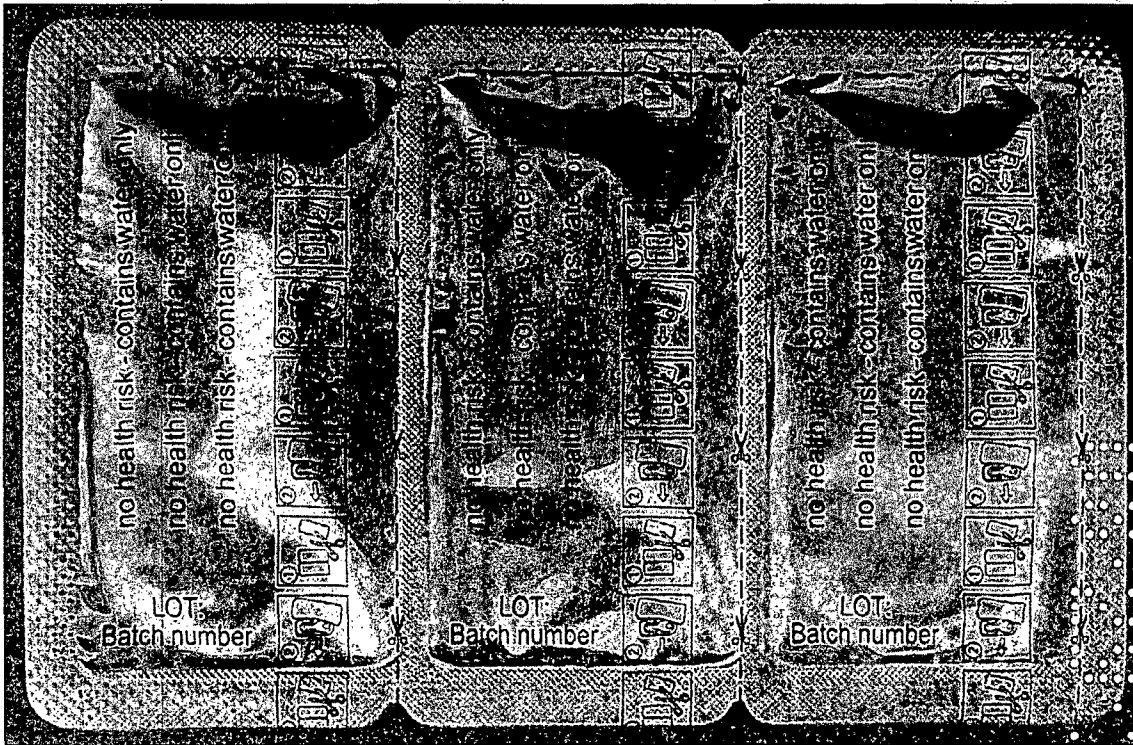
- 0.023 fl. oz.** - Use ONLY on Dogs & Puppies 6-22 lbs. and 8 weeks or older
- 0.045 fl. oz.** - Use ONLY on Dogs & Puppies 23-44 lbs. and 8 weeks or older
- 0.091 fl. oz.** - Use ONLY on Dogs & Puppies 45-88 lbs. and 8 weeks or older
- 0.136 fl. oz.** - Use ONLY on Dogs & Puppies 89-132 lbs. and 8 weeks or older

**Fipronil 9.8%**  
**(S)-Methoprene 8.8%**

[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

[Optional marketing claims]

[Picture of Dog or Puppy 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]

#### C668.2 for Dogs

The first time you treat your dog, 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 C668.2 for Dogs.

First Application Sticker: Apply C668.2 for Dogs

Month 1 Sticker: Apply C668.2 for Dogs

Month 2 Sticker: Apply C668.2 for Dogs

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

[For more information, visit [www.xxxxx.com](http://www.xxxxx.com)]

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

[Optional bar code]