



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 9, 2015

Ann M. Tillman
Agent for Horizon Valley Generics, Inc.
c/o Pyxis Regulatory Consulting, Inc.
4110 136th Street NW
Gig Harbor, WA 98332-9122

Subject: Label Amendment – Addition of Previously Approved/Revised Label Language
Product Name: C668.2 FOR DOGS
EPA Registration Number: 88052-13
Application Date: November 10, 2014
Decision Number: 497162

Dear Ms. Tillman:

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

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

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Maggie Rudick by phone at (703) 347-0257, or via e-mail at rudick.maggie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'KBD', enclosed within a hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

**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, Pet Works™ Plus for Dogs, PetLock™ Plus for Dogs, and PetAction™ Plus 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:

Fipronil9.8%
(S)-Methoprene.....8.8

OTHER INGREDIENTS:81.4%

TOTAL: 100.0%

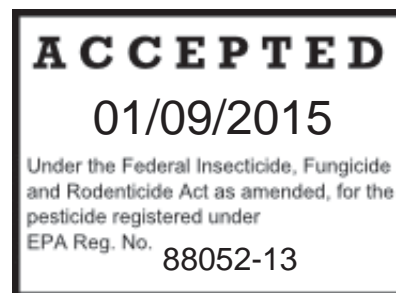
KEEP OUT OF REACH OF CHILDREN

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]))



[Manufactured for:

[Distributed by:]

Horizon Valley Generics, Inc.
8735 Rosehill Road
Kansas City, Missouri 64106]

[MADE IN Germany]

[C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.]

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[QUESTIONS OR COMMENTS ABOUT THIS PRODUCT]

[Call xxx-xxx-xxxx]

[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 HANDLING. 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 on your dog 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 of fleas on your dog 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.

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

[Manufactured for:
[Distributed by:]
Horizon Valley Generics, Inc.
8735 Rosehill Road
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]
[Product Bar Code]

(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

[Logos/Photos]



[Options for dog photos]



[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 which 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]
- [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 re-infestation of fleas on your dog for up to three months]

LABEL DIRECTIONS FOR PACKAGE INSERT

C668.2 FOR DOGS

[ALTERNATE BRAND NAMES: Springline® for Dogs, Springline® Spot-On for Dogs, Pet Works™ Plus for Dogs, PetLock™ Plus for Dogs, and PetAction™ Plus 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
OTHER INGREDIENTS:	<u>81.4%</u>
TOTAL:	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.

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.

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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.

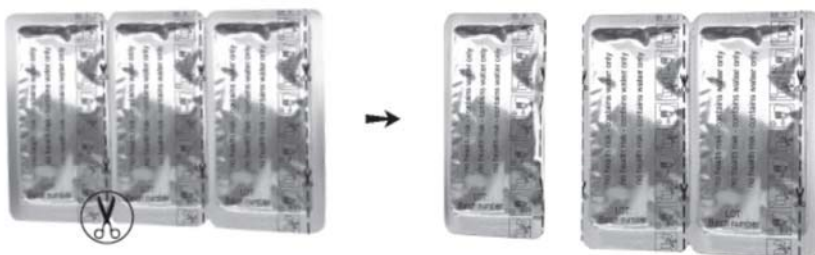
Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 6 pounds.

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 on your dog 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 of fleas on your dog 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

[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 HANDLING. 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:

[Distributed by:]

Horizon Valley Generics, Inc.

8735 Rosehill Road

Kansas City, Missouri 64106

MADE IN Germany

C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.

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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.; only number will appear]

CAT PROHIBITION ICON

DO NOT USE ON CATS

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.; only number will appear]

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.

Horizon Valley Generics, Inc.
8735 Rosehill Road
Kansas City, Missouri 64106

[Optional bar code]