



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

88052-15

Date of Issuance:

8/15/17

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 08/15/2019

Name of Pesticide Product:

C688.2 For Dogs

Name and Address of Registrant (include ZIP Code):

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

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

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

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

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

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

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

Date:

8/15/17

EPA Form 8570-6

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 08/15/2019.
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 04/19/2013.
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 01/08/2015

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.

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EPA Reg. No. 88052-15
Decision No. 524065, 528915

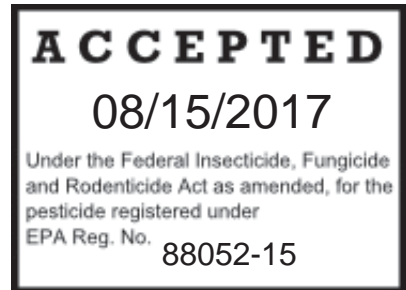
Enclosure

Primary brand name: 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]

Sublabel 1: 3- and 4- Count and 2 x 3-Count

Sublabel 2. 1-count



Sublabel 1: 3- and 4-Count and 2 x 3-Count

**Label Directions and Container including Carton, Overwrap of 2 x 3-Count
Cartons, Package Insert, Blister, and Optional 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

4 x 0.023 FL. OZ. PACKAGE

4 x 0.045 FL. OZ. PACKAGE

4 x 0.091 FL. OZ. PACKAGE

4 x 0.136 FL. OZ. PACKAGE

6 x 0.023 FL. OZ. PACKAGE

6 x 0.045 FL. OZ. PACKAGE

6 x 0.091 FL. OZ. PACKAGE

6 x 0.136 FL. OZ. PACKAGE

[FRONT PANEL OF 2 X 3-COUNT OVERWRAP]

C668.2 FOR DOGS

[“DOGS” will be at least 75% of the size of the largest letter of the brand name]

Use **ONLY** on dogs and puppies weighing [6-22] [23-44] [45-88] [89-132] lbs. and 8 weeks or older

Kills Fleas, Flea Eggs and Larvae, [and] 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 brackets [] or represents notes to reviewer - the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see list within the label.]

[A large, clear picture of a dog in the weight range for the product as packaged will appear on the front panel.]

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

See label insert within carton for FIRST AID, PRECAUTIONARY STATEMENTS and COMPLETE DIRECTIONS FOR USE

NET CONTENTS:

[Overwrap: 2 cartons each containing 0.069 fl. oz. [2.01 mL] [optional text: 3 doses per carton, 6 doses total]
[Overwrap: 2 cartons each containing 0.135 fl. oz. [4.02 mL] [optional text: 3 doses per carton, 6 doses total]
[Overwrap: 2 cartons each containing 0.273 fl. oz. [8.04 mL] [optional text: 3 doses per carton, 6 doses total]
[Overwrap: 2 cartons each containing 0.408 fl. oz. [12.06 mL] [optional text: 3 doses per carton, 6 doses total]

Manufactured for:

[Distributed by:]

Horizon Valley Generics, Inc.
8735 Rosehill Road, Suite 300
Lenexa, KS 66215

[MADE IN Germany]

[C668.2 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.]
[©20xx Horizon Valley Generics, Inc. All rights reserved.]

[QUESTIONS OR COMMENTS ABOUT THIS PRODUCT]

[Call xxx-xxx-xxxx]
[Product Bar Code]

[CAT PROHIBITION ICON is 1.5 cm x 1.5 cm, black colored icon on yellow background in a box in the lower right hand corner of the front panel.]



[FRONT PANEL OF CARTON]

C668.2 FOR DOGS [“DOGS” will be at least 75% of the size of the largest letter of the brand name]

Use **ONLY** on dogs and puppies weighing [6-22] [23-44] [45-88] [89-132] lbs. and 8 weeks or older

Kills Fleas, Flea Eggs and Larvae, [and] 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 brackets [] or represents notes to reviewer - the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see list within the label.

[A large, clear picture of a dog in the weight range for the product as packaged will appear on the front panel.]

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, PRECAUTIONARY STATEMENTS and COMPLETE DIRECTIONS FOR USE

NET CONTENTS:

[0.069 fl. oz. [2.01 mL] [optional text: 3 applicators each containing 0.023 fl. oz. [0.67 mL]; [3 Doses]

[0.135 fl. oz. [4.02 mL] [optional text: 3 applicators each containing 0.045 fl. oz. [1.34 mL]; [3 Doses]

[0.273 fl. oz. [8.04 mL] [optional text: 3 applicators each containing 0.091 fl. oz. [2.68 mL]; [3 Doses]

[0.408 fl. oz. [12.06 mL] [optional text: 3 applicators each containing 0.136 fl. oz. [4.02 mL]; [3 Doses]

[0.092 fl. oz. [2.68 mL] [optional text: 4 applicators each containing 0.023 fl. oz. [0.67 mL]; [4 Doses]

[0.180 fl. oz. [5.36 mL] [optional text: 4 applicators each containing 0.045 fl. oz. [1.34 mL]; [4 Doses]

[0.364 fl. oz. [10.72 mL] [optional text: 4 applicators each containing 0.091 fl. oz. [2.68 mL]; [4 Doses]

[0.544 fl. oz. [16.08 mL] [optional text: 4 applicators each containing 0.136 fl. oz. [4.02 mL]; [4 Doses]

[0.138 fl. oz. [4.02 mL] [optional text: 6 applicators each containing 0.023 fl. oz. [0.67 mL]; [6 Doses]

[0.270 fl. oz. [8.04 mL] [optional text: 6 applicators each containing 0.045 fl. oz. [1.34 mL]; [6 Doses]

[0.546 fl. oz. [16.08 mL] [optional text: 6 applicators each containing 0.091 fl. oz. [2.68 mL]; [6 Doses]

[0.816 fl. oz. [24.12 mL] [optional text: 6 applicators each containing 0.136 fl. oz. [4.02 mL]; [6 Doses]

Manufactured for:

[Distributed by:]

Horizon Valley Generics, Inc.

8735 Rosehill Road, Suite 300

Lenexa, KS 66215

[MADE IN Germany]

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

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

[QUESTIONS OR COMMENTS ABOUT THIS PRODUCT]

[Call xxx-xxx-xxxx]

[Product Bar Code]

[CAT PROHIBITION ICON is 1.5 cm x 1.5 cm, black colored icon on yellow background in a box in the lower right hand corner of the front panel.]



[BACK PANEL OF CARTON AND OF OVERWRAP OF 2 X 3-COUNT CARTONS]

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. 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.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. [The following text in parentheses represents the translation of the previous statement and will be present on the label.] (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you.)]

RESTRICTIONS

Do not use on cats, rabbits, or other animals.

Do not use on puppies under 8 weeks of age and less than [6][23][45][89] lbs.

Do not allow your dog to ingest this product.

Do not apply more frequently than once every 4 weeks.

Do not apply more than one applicator per treatment for one dog regardless of the dog's weight.

Do not bathe or allow your dog to swim for 24 hours after application.

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.

To kill adult fleas, flea eggs and larva, [and]chewing lice, [and 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 weighing [6-22][23-44][45-88][89-132] lbs as follows.

HOW TO OPEN

See label insert for opening instructions.

HOW TO APPLY

To apply C668.2 for Dogs: Your dog needs to be dry at the time of application and remain dry for 24 hours after application. 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. Do not apply more than one applicator per dog per treatment regardless of the dog's weight.

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 48 hours for up to 28 days.]

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

[The following text in a box will be placed in the lower right hand corner of back panel immediately above the cat warning text box.]

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.

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



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. 88052-15

EPA Est. No.

Manufactured for:

[Distributed by:]

Horizon Valley Generics, Inc.
8735 Rosehill Road, Suite 300
Lenexa, KS 66215

[MADE IN Germany]

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[QUESTIONS OR COMMENTS ABOUT THIS PRODUCT]

[Call xxx-xxx-xxxx]

[Product Bar Code]

[SIDE PANELS OF CARTON AND OF OVERWRAP OF 2 X 3-COUNT CARTONS]

Use **ONLY** on dogs and puppies weighing [6-22][23-44][45-88][89-132] lbs. and 8 weeks or older
[C668.2 for Dogs]
[EPA Reg. No. 88052-15]
Lot/Batch Number

[Example Logos/Photos]



[Options for dog photos; alternate brand name photos may vary]

[Optional Marketing Claims for Carton, Overwrap of 2 x 3-count Cartons, and Package Insert]

[Fleas, Ticks, Chewing Lice]

1. [[Fast-acting], [long-lasting], [waterproof], [convenient] spot treatment for control of [fleas], [flea eggs] & [flea larvae], [ticks], [mosquitoes], and [chewing lice]]
2. [Kills ticks that may transmit Lyme disease]
3. [Waterproof]
4. [C668.2 FOR DOGS provides [convenient] and [effective] [flea], [tick], [chewing lice], and [mosquito] control for [dogs] and [puppies weighing [6-22][23-44][45-88][89-132] lbs and on puppies under 8 weeks of age]]
5. [[Fast acting] and [long-lasting]]
6. [Waterproof]
7. [Convenient to use]
8. [Kills [fleas], [flea eggs] and [flea larvae]]
9. [Prevents all flea stages [eggs, larvae, pupae] from developing]
10. [Controls fleas which may cause [flea allergy dermatitis] [FAD]]
11. [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]] [Text in parentheses represents the Latin name of pest and the text is meant to be included on label.]
12. [Rapidly controls infestations of chewing lice]
13. [Kills mosquitoes]
14. [Aids in control of sarcoptic mange mite infestations]
15. [Can be used on [breeding], [pregnant] and [lactating] bitches]
16. [Waterproof [water resistant]]
17. [Kills fleas which may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
18. [Effective monthly treatment of [fleas], [ticks], [lice] and [mosquitoes]]
19. [Remains effective after [bathing] and [swimming]]
20. [Kills ticks that may transmit [Lyme disease], [Rocky Mountain spotted fever], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis]]
21. [[Easy], [fast], [effective] control of [fleas], [ticks], [lice] and [mosquitoes]]
22. [Kills [fleas]. [ticks], [lice]]
23. [Kills fleas that may cause flea bite anemia]
24. [Optional graphics: Picture of Adult Fleas]
25. [Optional graphics: Picture of Flea Eggs]
26. [Optional graphics: Picture of Flea Larvae]
27. [Optional graphics: Picture of Tick]
28. [Optional graphics: Picture of Louse]
29. [Optional graphics: Picture of Mosquito]
30. [Convenient to use]
31. [Long lasting]
32. [Fast acting]
33. Controls infestations with chewing lice]
34. [Kills mosquitoes]
35. [Kills all stages of deer ticks]
36. [Apply monthly]
37. [Aids in the control of sarcoptic mange mites]
38. [Best results when used monthly [year round]]
39. [For year round protection of fleas, ticks and chewing lice]
40. [Kills newly emerged fleas before they lay eggs]

41. [Calendar stickers inside]
42. [3 Pack] [3 Applicators][3 Months Supply][3 Doses]
43. [4 Pack] [4 Applicators][4 Months Supply][4 Doses]
44. For overwrap package only: [6 Pack] [6 Applicators][6 Months Supply][6 Doses]
45. For overwrap package only: [Value Pack]
46. [4 Dose Value Pack]
47. For overwrap package only: [6 Dose Value Pack]
48. [Controls flea re-infestation for up to three months]
49. [Contains the same active ingredients fipronil and (S)-methoprene found in Frontline® Plus for Dogs]
50. [Contains Fipronil and (S)-Methoprene [the same active ingredients used in Frontline® Plus for Dogs]]
51. [Contains the same active ingredients as Frontline® Plus for Dogs]
52. [Note to reviewer: whenever any of the three claims immediately above are included on product labels, then the label will contain the appropriate disclaimers below. The disclaimers will be placed in the same area of the label as the optional claims so that both are viewed together.]
53. [C668.2 FOR DOGS is not manufactured by or distributed by Merial Limited.]
54. [Frontline® Plus is a registered trademark of Merial Limited.]

[LABEL DIRECTIONS FOR PACKAGE INSERT]

C668.2 FOR DOGS

["DOGS" will be at least 75% of the size of the largest letter of the brand name]

[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] [23-44] [45-88] [89-132] lbs. and 8 weeks or older

Kills Fleas, Flea Eggs and Larvae, [and]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 dogs or puppies less than [6][23][45][89] 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.

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. [The following text in parentheses represents the translation of the previous statement and will be present on the label.] (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).

RESTRICTIONS

Do not use on cats, rabbits, or other animals.

Do not use on puppies under 8 weeks of age and less than [6][23][45][89] lbs.

Do not allow your dog to ingest this product.

Do not apply more frequently than once every 4 weeks.

Do not apply more than one applicator per treatment for one dog regardless of the dog's weight.

Do not bathe or allow your dog to swim for 24 hours after application.

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 [The following text in parentheses will be present on the label. *minimum weight based on the package size:* [6 pounds (0.23 fl. oz.)][23 pounds (0.045 fl. oz.)][45 pounds (0.091 fl. oz.)][89 pounds (0.1136 fl. oz.)]. Do not use more than one applicator per dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.

To kill adult fleas, flea eggs and larva, [and] chewing lice, [and 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 weighing [6-22][23-44][45-88][89-132] lbs as follows.

[Opening instructions for 3-count and 2 X 3-Count]



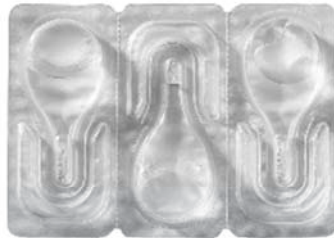
HOW TO OPEN

OPENING INSTRUCTIONS FOR USE



Klocke Verpackungsservice GmbH
www.klocke.com

1 Tear through perforation



2 Fold back the safety tab



3 Cut with scissors to open applicator

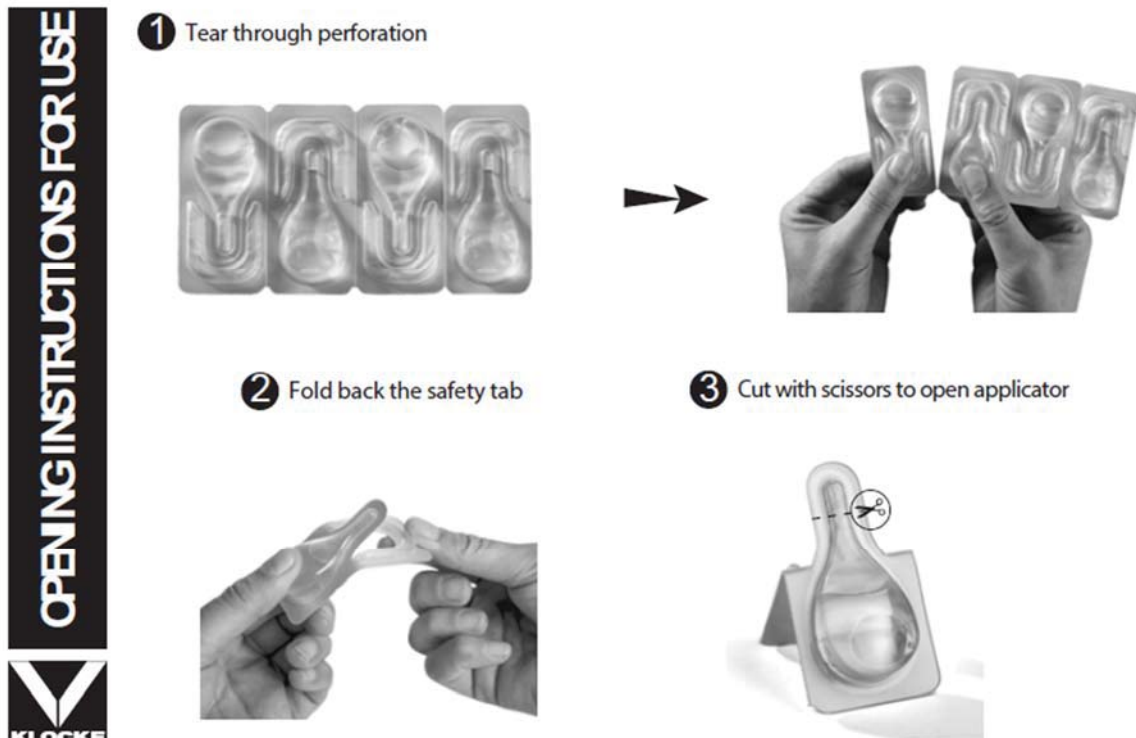


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[Opening Instructions for 4 count]



HOW TO OPEN



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HOW TO APPLY

To apply C668.2 for Dogs: Your dog needs to be dry at the time of application and remain dry for 24 hours after application. 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. Do not apply more than one applicator per dog per treatment regardless of the dog's weight.

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 48 hours for up to 28 days.]

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

[CAT PROHIBITION ICON size is 1.5 cm x 1.5 cm, black colored icon on white background in a box in the lower right hand corner of the package insert]



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. 88052-15

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 or 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.

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, Suite 300
Lenexa, KS 66215

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 Applicator]

KEEP OUT OF REACH OF CHILDREN

CAUTION.

Read entire label before use.

C668.2 for Dogs [“DOGS” will be at least 75% of the size of the largest letter of the brand name]

EPA Reg. No. 88052-15

Lot No.

CAT PROHIBITION ICON

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%

[Text for Optional Reminder Stickers for 3-count, 4-count, and 6-count Packages]

[Optional marketing claims]

[Picture of Dog or Puppy 8 weeks or older in weight range of product as packaged]

[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 [“DOGS” will be at least 75% of the size of the largest letter of the brand name]

The first time you treat your dog, place the First Application Sticker on your calendar. Apply Stickers [2 and 3] [2 through 4] [2 through 6] to the calendar [30 and 60 days] [30, 60, and 90 days] [30, 60, 90, 120, and 150 days] [at the end of each 30 day period] 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 2 Sticker: Apply C668.2 for Dogs

Month 3 Sticker: Apply C668.2 for Dogs

[Month 4 Sticker: Apply C668.2 for Dogs]

[Month 5 Sticker: Apply C668.2 for Dogs]

[Month 6 Sticker: Apply C668.2 for Dogs]

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

Horizon Valley Generics, Inc.
8735 Rosehill Road, Suite 300
Lenexa, KS 66215

[Optional bar code]

Sublabel 2. 1-Count

Label Directions and Container Carton, Package Insert, and Blister for

1 x 0.023 FL. OZ. PACKAGE

1 x 0.045 FL. OZ. PACKAGE

1 x 0.091 FL. OZ. PACKAGE

1 x 0.136 FL. OZ. PACKAGE

[FRONT PANEL OF CARTON]

C668.2 FOR DOGS

[“DOGS” will be at least 75% of the size of the largest letter of the brand name]

Use **ONLY** on dogs and puppies weighing [6-22] [23-44] [45-88] [89-132] lbs. and 8 weeks or older

Kills Fleas, Flea Eggs and Larvae, [and] 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 brackets [] or represents notes to reviewer - the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see list within the label.]

[A large, clear picture of a dog in the weight range for the product as packaged will appear on the front panel.]

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 within carton for FIRST AID, PRECAUTIONARY STATEMENTS, STORAGE AND DISPOSAL, and COMPLETE DIRECTIONS FOR USE

NET CONTENTS:

[1 applicator containing 0.023 fl. oz. [1 dose per carton]]

[1 applicator containing 0.045 fl. oz. [1 dose per carton]]

[1 applicator containing 0.091 fl. oz. [1 dose per carton]]

[1 applicator containing 0.136 fl. oz. [1 dose per carton]]

[CAT PROHIBITION ICON is 1.5 cm x 1.5 cm, black colored icon on yellow background in a box in the lower right hand corner of the front panel.]



[BACK PANEL OF CARTON]

C668.2 FOR DOGS 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.

For complete Directions For Use, How to Open and How to Apply, see label insert.

[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.]

RESTRICTIONS

Do not use on cats, rabbits, or other animals.

Do not use on puppies under 8 weeks of age and less than [6][23][45][89] lbs.

Do not allow your dog to ingest this product.

Do not apply more frequently than once every 4 weeks.

Do not apply more than one applicator per treatment for one dog regardless of the dog's weight.

Do not bathe or allow your dog to swim for 24 hours after application.

FIRST AID

See label insert within carton.

[The following text in a box will be placed in the lower right hand corner of back panel immediately above the cat warning text box.]

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.

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



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.

Manufactured for:

[Distributed by:]

Horizon Valley Generics, Inc.
8735 Rosehill Road, Suite 300
Lenexa, KS 66215

[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]

EPA Reg. No. 88052-15

EPA Est. No.

[SIDE PANELS OF CARTON]

Use **ONLY** on dogs and puppies weighing [6-22][23-44][45-88][89-132] lbs. and 8 weeks or older
[C668.2 for Dogs]
[EPA Reg. No. 88052-15]
Lot/Batch Number

[Optional Marketing Claims for Carton and Package Insert]

[Fleas, Ticks, Chewing Lice]

1. [[Fast-acting], [long-lasting], [waterproof], [convenient] spot treatment for control of [fleas], [flea eggs] & [flea larvae], [ticks], [mosquitoes], and [chewing lice]]
2. [Kills ticks that may transmit Lyme disease]
3. [Waterproof]
4. [C668.2 FOR DOGS provides [convenient] and [effective] [flea], [tick], [chewing lice], and [mosquito] control for [dogs] and [puppies weighing [6-22][23-44][45-88][89-132] lbs and on puppies under 8 weeks of age]]
5. [[Fast acting] and [long-lasting]]
6. [Waterproof]
7. [Convenient to use]
8. [Kills [fleas], [flea eggs] and [flea larvae]]
9. [Prevents all flea stages [eggs, larvae, pupae] from developing]
10. [Controls fleas which may cause [flea allergy dermatitis] [FAD]]
11. [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]] [Text in parentheses represents the Latin name of pest and the text is meant to be included on label.]
12. [Rapidly controls infestations of chewing lice]
13. [Kills mosquitoes]
14. [Aids in control of sarcoptic mange mite infestations]
15. [Can be used on [breeding], [pregnant] and [lactating] bitches]
16. [Waterproof [water resistant]]
17. [Kills fleas which may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
18. [Effective monthly treatment of [fleas], [ticks], [lice] and [mosquitoes]]
19. [Remains effective after [bathing] and [swimming]]
20. [Kills ticks that may transmit [Lyme disease], [Rocky Mountain spotted fever], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis]]
21. [[Easy], [fast], [effective] control of [fleas], [ticks], [lice] and [mosquitoes]]
22. [Kills [fleas]. [ticks], [lice]]
23. [Kills fleas that may cause flea bite anemia]
24. [Optional graphics: Picture of Adult Fleas]
25. [Optional graphics: Picture of Flea Eggs]
26. [Optional graphics: Picture of Flea Larvae]
27. [Optional graphics: Picture of Tick]
28. [Optional graphics: Picture of Louse]
29. [Optional graphics: Picture of Mosquito]
30. [Convenient to use]
31. [Long lasting]
32. [Fast acting]
33. Controls infestations with chewing lice]
34. [Kills mosquitoes]
35. [Kills all stages of deer ticks]
36. [Apply monthly]
37. [Aids in the control of sarcoptic mange mites]
38. [Best results when used monthly [year round]]
39. [Kills newly emerged fleas before they lay eggs]
40. [1 Applicator][1 Month Supply][1 Dose]
41. [Contains the same active ingredients fipronil and (S)-methoprene found in Frontline® Plus for Dogs]

42. [Contains Fipronil and (S)-Methoprene [the same active ingredients used in Frontline® Plus for Dogs]]
43. [Contains the same active ingredients as Frontline® Plus for Dogs]
44. [Note to reviewer: whenever any of the three claims immediately above are included on product labels, then the label will contain the appropriate disclaimers below. The disclaimers will be placed in the same area of the label as the optional claims so that both are viewed together.]
45. [C668.2 FOR DOGS is not manufactured by or distributed by Merial Limited.]
46. [Frontline® Plus is a registered trademark of Merial Limited.]

[LABEL DIRECTIONS FOR PACKAGE INSERT]

C668.2 FOR DOGS

[“DOGS” will be at least 75% of the size of the largest letter of the brand name]

Use **ONLY** on dogs and puppies weighing [6-22] [23-44] [45-88] [89-132] lbs. and 8 weeks or older

Kills Fleas, Flea Eggs and Larvae, [and] 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: 81.4%

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 dogs or puppies less than [6][23][45][89] 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.

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. [The following text in parentheses represents the translation of the previous statement and will be present on the label. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you).]

RESTRICTIONS

Do not use on cats, rabbits, or other animals.

Do not use on puppies under 8 weeks of age and less than [6][23][45][89] lbs.

Do not allow your dog to ingest this product.

Do not apply more frequently than once every 4 weeks.

Do not apply more than one applicator per treatment for one dog regardless of the dog's weight.

Do not bathe or allow your dog to swim for 24 hours after application.

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 [The text in parentheses will be present on the label. *minimum weight based on the package size:* [6 pounds (0.23 fl. oz.)][23 pounds (0.045 fl. oz.)][45 pounds (0.091 fl. oz.)][89 pounds (0.1136 fl. oz.)]. Do not use more than one applicator per dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.

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 and weighing [6-22][23-44][45-88][89-132] lbs as follows.

[Opening instructions for 1-count]



HOW TO OPEN

1 Fold back the safety tab



2 Cut with scissors to open applicator

HOW TO APPLY

To apply C668.2 for Dogs: Your dog needs to be dry at the time of application and remain dry for 24 hours after application. 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. Do not apply more than one applicator per dog per treatment regardless of the dog's weight.

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 48 hours for up to 28 days.]

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

CAT PROHIBITION ICON size is 1.5 cm x 1.5 cm, black colored icon on white background in a box in the lower right hand corner of the package insert]



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. 88052-15

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 or 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.

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, Suite 300

Lenexa, KS 66215

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 Applicator]

KEEP OUT OF REACH OF CHILDREN

CAUTION.

Read entire label before use.

C668.2 for Dogs [“DOGS” will be at least 75% of the size of the largest letter of the brand name]

EPA Reg. No. 88052-15

Lot No.

CAT PROHIBITION ICON

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%