

88051-2

06/25/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Tuesday, June 25, 2013

Chanelle Pharmaceuticals Manufacturing Ltd.
c/o Terry McNamara
Exponent, Inc.
Managing Regulatory Consultant
Center for Chemical Regulation and Food Safety
1150 Connecticut Avenue NW, Suite 1100
Washington, DC 20036

Subject: Submission of an R340 label amendment with data to change the age limitation from 12 weeks to 8 weeks of age.

EPA Registration No.: 88051-2 (Zeronil Spot-on Solution for Dogs)

PRIA Decision: R340

Decision No.: 470010

Date of submission: September 21, 2012

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). The terms of registration as set forth in the original Notice of Registration dated August 30, 2012 remain in effect until rescinded by the Agency.

Chanelle Pharmaceuticals Manufacturing Ltd. must submit/cite all data required for registration / reregistration/ registration review of your product under the Federal Fungicide, Insecticide and Rodenticide Act (FIFRA) section 3(c)(5) or 4(a) when the Agency requires registrants of similar products to submit such data.

You must furnish 2 copies of the final printed label (mock labels) for the agency records.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e).

A stamped copy of the label is enclosed for your records.

Sincerely,

A handwritten signature in black ink that reads "Richard J. Gebken".

Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505C)

Enclosure

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[] – Denotes optional statements and/or images.

{Master Label}

Zeronil Spot-On Solution for Dogs

FOR USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE OR OLDER AND 7 LBS OR OVER

[[Brand Name] provides protection that controls fleas, ticks, sarcoptic mange mites, chewing lice, and mosquitoes. Controls deer ticks that may transmit Lyme disease. Controls brown dog ticks, American dog ticks, and lone star ticks. Prevents flea reinfestation.]

[[Brand Name] provides an easy to use spot treatment for quick-acting, long-lasting control of fleas, ticks, sarcoptic mites, chewing lice and mosquitoes.]

[[Brand Name] for dogs [&] [and] puppies 8 weeks of age or older. Easy to use spot treatment for quick-acting, long lasting control of fleas, ticks, sarcoptic mites, chewing lice and mosquitoes.]

[[Brand Name] provides easy to use and effective flea, tick, sarcoptic mites, chewing lice and mosquito control for dogs and puppies over 8 weeks of age or older.]

[For use ONLY on dogs [7-22 lbs.][23-44 lbs.][45-88 lbs.][89-132 lbs.] [over 8 weeks of age or older].]

[For use on Dogs & Puppies 8 weeks of age or older and] [7-22lbs.]

[For use on Dogs 23-44 lbs.]

[For use on Dogs 45-88 lbs.]

[For use on Dogs 89-132 lbs.]

ACTIVE INGREDIENT:

Fipronil.....9.70%

OTHER INGREDIENT: 90.30%

TOTAL 100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION
READ ENTIRE LABEL BEFORE EACH USE**

[1.5 cm X 1.5 cm] cat prohibition icon

ACCEPTED
JUN 25 2013
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 88051-2

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS CAUTION: Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. 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. Do not use on puppies under 8 weeks of age ~~or older~~. Individual sensitivities, while rare, may occur after using ANY pesticide product. Some 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 immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs.

FIRST AID	
If swallowed:	<ul style="list-style-type: none"> • Call a poison control center or a doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call 1-800-XXX-XXXX.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

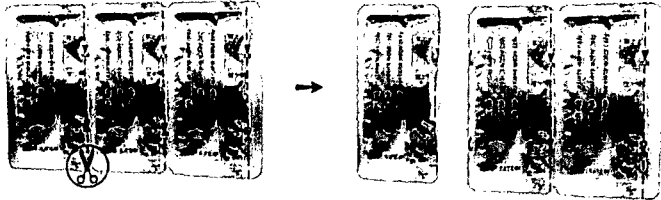
DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT.

To control fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, deer ticks (which may carry Lyme disease), sarcoptic mites, chewing lice and mosquitoes, apply only on

dogs and puppies (8 weeks of age or older) as follows:

DIRECTIONS FOR OPENING PACKAGING:

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



DIRECTIONS FOR APPLICATION OF PRODUCT:

1. Place applicator tip through the dog's hair to the skin level between the shoulder blades.
2. Squeeze the applicator, applying entire contents in a single spot to the dog's skin. Avoid applying product superficially to the dog's hair.

Use Only one applicator per treatment.

[Brand Name] can also be used for the treatment and protection from mosquitoes, fleas, ticks, sarcoptic mites, and chewing lice infestations on puppies as young as 8 weeks old.

[Brand Name] continues to work even after bathing, water immersion, or exposure to sunlight.

FREQUENCY OF APPLICATION:

When used as directed on a monthly basis, [Brand Name] will completely control flea, tick, mosquito, and chewing lice infestations.

Do not reapply [Brand Name] for [[4] [four] weeks] [30 days] [[1][one] month] on dogs.

Fleas – Studies show that [Brand Name] controls adult fleas for up to [three] [3] months. Although [Brand Name] can protect against adult fleas for up to [three] [3] months, if there is a high risk of reinfestation or if the dog has fleas which can cause flea allergy dermatitis, a once a month application may be necessary.

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**Chanelle Dog Fipronil-Only Spot-On
ver. 6 (07-Jan-2013)**

Ticks – [Brand Name] controls ticks for up to one month. Apply once a month to control ticks. [Brand Name] can control all three life stages of ticks (larva, nymph, and adult).

Mites - [Brand Name] helps control mites that cause sarcoptic mange. Continual treatments over several months are recommended for the complete elimination of mites.

Mosquitoes – [Brand Name] controls mosquitoes within 24 hours for up to [1 week] [7 days] and within 48 hours for up to [one month] [28 days].

[Brand Name] continues to work even after bathing, water immersion, or exposure to sunlight. Avoid contact with treatment area until dry. Do not reapply [Brand Name] for at least [one month] [30 days] [4 weeks].

Only For Dogs Weighing 7-22 lbs. Do not apply to dogs weighing less than 7 lbs. [which includes small dogs and puppies, 8 weeks of age or older]:

{For boxes containing 0.67 mL (0.023 fl. oz.) applicators in blister packs}

Apply one applicator (0.67 mL) (0.023 fl. oz.) as a single spot on the dog's skin between the shoulder blades.

Only For Dogs Weighing 23 - 44 lbs.

{For boxes containing 1.34 mL (0.045 fl. oz.) applicators in blister packs}

Apply one applicator (1.34 ml) (0.045 fl. oz.) as a single spot on the dog's skin between the shoulder blades.

Only For Dogs Weighing 45 – 88 lbs.

{For boxes containing 2.68 mL (0.091 fl. oz.) applicators in blister packs }

Apply one applicator (2.68 ml) (0.091 fl. oz.) as a single spot on the dog's skin between the shoulder blades.

Only For Dogs Weighing 89 - 132 lbs. Do not double dose dogs larger than 132 lbs

{For boxes containing 4.02 mL (0.136 fl. oz.) applicators in blister packs}

Apply one applicator (4.02 ml) (0.136 fl. oz.) as a single spot on the dog's skin between the shoulder blades.

Side Effects: Monitor your dog after application. Side effects may include signs of 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 1-800-XXX-XXXX.

[1.5 cm x 1.5 cm] 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.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F/[/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL:

If empty: Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY AND DISCLAIMER

Read the entire Label, including the Precautionary Statements, First Aid, Use Directions and Warranty Disclaimer before using this Product. Use of this product constitutes acceptance of this warranty by the user or buyer. The directions for use on this product label are believed to be sufficient and must be followed carefully with every use. Elimination of all risks associated with the use of this product is impossible. Because of factors unforeseen, unintended consequences may result when using this product. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer. Chanelle Pharmaceuticals Manufacturing Ltd. makes a commitment to providing high quality products to consumers. To the extent consistent with applicable law, Chanelle Pharmaceuticals Manufacturing Ltd. makes no other express or implied warranty of merchantability or fitness for a particular purpose or any other express or implied warranty. To the extent consistent with applicable law, the exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories) shall be limited to, at Chanelle Pharmaceuticals Manufacturing Ltd.'s election, one of the following:

- (1) Refund of purchase price paid by buyer or user for product bought, or
- (2) Replacement of amount of product used.

To the extent consistent with applicable law, Chanelle Pharmaceuticals Manufacturing Ltd. shall not be liable for losses or damages resulting from handling or use of this product unless Chanelle Pharmaceuticals Manufacturing Ltd. is promptly notified of such losses or damages in writing. In no case shall Chanelle Pharmaceuticals Manufacturing Ltd. be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Chanelle Pharmaceuticals Manufacturing Ltd. or the seller is authorized to vary or exceed the terms of this Warranty Disclaimer in any manner.]

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**Chanelle Dog Fipronil-Only Spot-On
ver. 6 (07-Jan-2013)**

Distributed by:
Chanelle Pharmaceuticals Manufacturing Ltd.
Dublin Road
Loughrea, Co., Galway
Ireland
EPA Reg. No. 88051-2
EPA Est. No. 74720-DEU-001

[BAR CODE AREA]

[CHANELLE BRAND LOGO]

Chanelle Pharmaceuticals Manufacturing Ltd.:

Zeronil Spot-On Solution for Dogs

FOR USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE OR OLDER AND 7 LBS OR OVER

[[Brand Name] provides an easy to use and effective flea, tick, sarcoptic mite, chewing lice and mosquito protection for dogs and puppies 8 weeks of age or older]

[Mosquitoes]

- [Controls mosquitoes within 24 hours for up to [7 days][1 week]] [and within 48 hours for up to [28 days][one month]]
- [Controls mosquitoes]

[Adult Fleas]

- [Controls adult fleas for up to [3 months][90 days]]
- [Controls adult fleas Up to [4 weeks] [1 month] [30 days]!]
- [Dogs with a high risk for flea reinfestation should be retreated once monthly]
- [Controls adult fleas which may cause flea [allergy dermatitis][,] [and] [bite anemia].]
- [Controls newly emerged adult fleas before they lay eggs]

[Ticks]

- [Controls ticks including those that may transmit Lyme disease]
- [Controls Ticks for Up to [4 weeks] [1 month] [30 days]!]
- [Controls Deer Ticks (that may carry Lyme disease) for up to [4 weeks] [1 month] [30 days]]
- [Controls Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
- [Controls [brown dog ticks][,] [(*Rhipicephalus sanguineus*)][,] [American dog ticks][,] [and] [lone star ticks][.] [for up to [4 weeks] [1 month] [30 days].]]
- [Controls [Brown][,] [American][,] [and] [Lone Star] Dog Ticks[.] [for up to [4 weeks] [1 month] [30 days].]]
- [Controls all stages of brown dog ticks (larva, nymph and adult), American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)]
- [Controls American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[Multiple Infestations]

- [Eliminates chewing lice [and aids in the control of sarcoptic mange mites]]
- [Quickly halts chewing lice infestations]
- [Aids in the control of sarcoptic mange mite infestations that may cause sarcoptic mange.]
- [Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old and older]
- [Controls fleas, ticks, mosquitoes [&] [and] chewing lice]
- [Controls fleas, ticks, chewing lice, and mosquitoes]
- [Once a month flea, tick, mosquito and chewing lice protection]
- [Four] [4] Way [Action][Controls] [fleas, ticks, mosquitoes, and chewing lice]
- [[4 Week] [1 month] [30 day] [Flea and Tick [&] [and] Application]
- [[Four (4) Week] [1 month] [Flea, Tick, Mosquito and Chewing Lice Protection]
- [Monthly Flea and Tick Treatment]
- [Use **[Brand Name]** once a month to protect from ticks, sarcoptic mange mites, and chewing lice]
- [Once a month flea, tick, mosquito, and chewing lice protection.]
- [Controls Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]

[All Others]

- [For use on Dogs & Puppies 8 weeks of age or older]
- [Only use on Dogs [7-22lbs.][23-44 lbs.][45-88 lbs.][89-132 lbs.].
- [Easy to Use].
- [Quick Acting]
- [Long Lasting]
- [Waterproof]
- [Continues to work even after bathing]
- [Apply once every [4 weeks] [1 month] [30 days]!]
- [Protects against reinfestation]
- [Controls fleas which may cause flea allergy dermatitis]
- [Controls newly emerged adult fleas before they lay eggs]
- [Controls all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)]
- [Controls mosquitoes]
- [Quickly halts chewing lice infestations]
- [Controls sarcoptic mange mites that may cause sarcoptic mange]
- [Can be used on puppies 8 weeks of age or older]
- [For use on dogs [7-22lbs.] [23-44 lbs.] [45-88 lbs.] [89-132 lbs.]]
- [Contains Fipronil (9.7%)]

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{START - FRONT PANEL OF PACKAGING}

FOR USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE OR OLDER AND 7 LBS OR OVER

[[Brand Name] for dogs [&] [and] puppies 8 weeks of age or older. Easy to use spot treatment for quick-acting, long lasting protection from fleas, ticks, sarcoptic mange mites, chewing lice and mosquitoes.]

ACTIVE INGREDIENT:

Fipronil..... 9.70%

OTHER INGREDIENT: 90.30%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Side] [Back] Panel For Additional Precautionary Statements

**NET CONTENTS: 0.069 fl. oz. (2.01 mL) ([Three] [3] 0.023 fl. oz. (0.67 mL) applicators)
0.135 fl. oz. (4.02 mL) ([Three] [3] 0.045 fl. oz. (1.34 mL) applicators)
0.273 fl. oz. (8.04 mL) ([Three] [3] 0.091 fl. oz. (2.68 mL) applicators)
0.408 fl. oz. (12.06 mL) ([Three] [3] 0.136 fl. oz. (4.02 mL) applicators)**

[1.5 cm X 1.5 cm]

Cat prohibition icon in a box

{END - FRONT PANEL OF PACKAGING}

{START – BACK/SIDE PANEL OF PACKAGING}

[[Brand Name] contains the active ingredient fipronil that targets fleas, ticks, sarcoptic mange mites, chewing lice and mosquitoes.][Fipronil pools in the oils of the skin and hair follicles, and continuously releases from hair follicles onto the skin and coat, resulting in long-lasting protection.]

[Use ONLY on dogs or puppies [7-22 lbs.][23-44 lbs.][45-88 lbs.][89-132 lbs.] over 8 weeks of age or older.]

[Brand Name]

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE OR OLDER

[[Brand Name] provides control and protection against fleas, ticks, mosquitoes, sarcoptic mange

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mites, and chewing lice. Controls deer ticks that may transmit Lyme disease. Controls brown dog ticks, American dog ticks, and lone star ticks. Will prevent flea reinfestation for [[4][four] weeks] [[1][one] month] [30 days].]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS CAUTION: Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. 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. Do not use on puppies under 8 weeks of age ~~or older~~. Individual sensitivities, while rare, may occur after using any pesticide product. Some 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 immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs.

FIRST AID	
If swallowed:	<ul style="list-style-type: none"> • Call a poison control center or a doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call 1-800-XXX-XXXX.	

[[Brand Name] provides easy to use and effective flea, tick, sarcoptic mange mite, chewing lice and mosquito protection for dogs and puppies 8 weeks of age or older]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

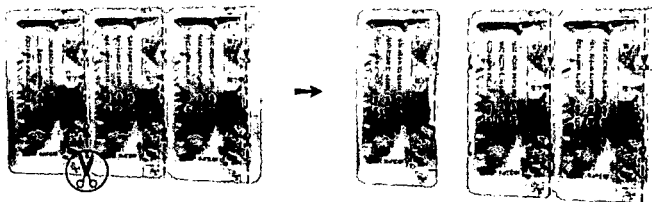
**Chanelle Dog Fipronil-Only Spot-On
ver. 6 (07-Jan-2013)**

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT.

To eliminate fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, deer ticks (which may carry Lyme disease), sarcoptic mites, chewing lice and mosquitoes, apply only on dogs and puppies (8 weeks of age or older) as follows:

DIRECTIONS FOR OPENING PACKAGING:

- 1** Cut along scissor cut line to separate unit



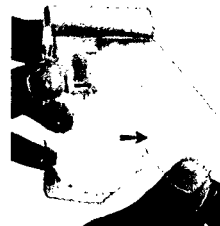
- 2** Turn unit over and cut corner at bulb end



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



- 4** Remove the applicator



DIRECTIONS FOR APPLICATION OF PRODUCT:

1. Place applicator tip through the dog's hair to the skin level between the shoulder blades.
2. Squeeze the applicator, applying entire contents in a single spot to the dog's skin. Avoid applying product superficially to the dog's hair.

Use only one applicator per treatment.

FREQUENCY OF APPLICATION:

When used as directed on a monthly basis, [Brand Name] will completely control flea, tick chewing lice, and mosquito infestations.

Fleas – Studies show that [Brand Name] controls adult fleas for up to [3][three] months. Although [Brand Name] protects dogs from fleas for up to [3][three] months, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis or flea bite

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anemia, a once a month application may be necessary.

Ticks – [Brand Name] controls ticks for up to one month. A once a month application is recommended where tick control is desired. [Brand Name] can all three life stages of ticks (larva, nymph, and adult).

Mites - [Brand Name] helps control sarcoptic mange mites that cause sarcoptic mange. Continual treatments over several months are recommended for the complete elimination of mites.

Mosquitoes – [Brand Name] controls mosquitoes within 24 hours for up to [1 week] [7 days] and within 48 hours for up to [one month] [28 days].

[Brand Name] continues to work even after bathing, water immersion, or exposure to sunlight. Avoid contact with treatment area until dry. Do not reapply [Brand Name] for at least [one month] [30 days] [4 weeks].

Only For Dogs Weighing 7 - 22 lbs. Do not apply to dogs weighing less than 7 lbs. [which includes small dogs and puppies, 8 weeks of age or older]:

{For boxes containing 0.67 mL (0.023 fl. oz.) applicators in blister packs}

Apply one applicator (0.67 mL) (0.023 fl. oz.) as a single spot on the dog's skin between the shoulder blades.

Only For Dogs Weighing 23 - 44 lbs.

{For boxes containing 1.34 mL (0.045 fl. oz.) applicators in blister packs}

Apply one applicator (1.34 ml) (0.045 fl. oz.) as a single spot on the dog's skin between the shoulder blades.

Only For Dogs Weighing 45 – 88 lbs.

{For boxes containing 2.68 mL (0.091 fl. oz.) applicators in blister packs }

Apply one applicator (2.68 ml) (0.091 fl. oz.) as a single spot on the dog's skin between the shoulder blades.

Only For Dogs Weighing 89 - 132 lbs. Do not double dose on dogs larger than 132 lbs.

{For boxes containing 4.02 mL (0.136 fl. oz.) applicators in blister packs}

Apply one applicator (4.02 ml) (0.136 fl. oz.) as a single spot on the dog's skin between the shoulder blades.

Side Effects: Monitor your dog after application. Side effects may include signs of 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 1-800-XXX-XXXX.

[1.5 cm x 1.5 cm] 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.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F/[25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL:

If empty: Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE: Keep away from heat and open flame.

[WARRANTY DISCLAIMER

Read the entire Label, including the Precautionary Statements, First Aid, Use Directions and Warranty Disclaimer before using this Product. Use of this product constitutes acceptance of this warranty by the user or buyer. The directions for use on this product label are believed to be sufficient and must be followed carefully with every use. Elimination of all risks associated with the use of this product is impossible. Because of factors unforeseen, unintended consequences may result when using this product. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer. Chanelle Pharmaceuticals Manufacturing Ltd. makes a commitment to providing high quality products to consumers. To the extent consistent with applicable law, Chanelle Pharmaceuticals Manufacturing Ltd. makes no other express or implied warranty of merchantability or fitness for a particular purpose or any other express or implied warranty. To the extent consistent with applicable law, the exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories) shall be limited to, at Chanelle Pharmaceuticals Manufacturing Ltd.'s election, one of the following:

- (1) Refund of purchase price paid by buyer or user for product bought, or
- (2) Replacement of amount of product used.

To the extent consistent with applicable law, Chanelle Pharmaceuticals Manufacturing Ltd. shall not be liable for losses or damages resulting from handling or use of this product unless Chanelle Pharmaceuticals Manufacturing Ltd. is promptly notified of such losses or damages in writing. In no case shall Chanelle Pharmaceuticals Manufacturing Ltd. be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Chanelle Pharmaceuticals Manufacturing Ltd. or the seller is authorized to vary or exceed the terms of this Warranty Disclaimer in any manner.]

Distributed by:
Chanelle Pharmaceuticals Manufacturing Ltd.
Dublin Road
Loughrea, Co., Galway
Ireland
EPA Reg. No. 88051-2
EPA Est. No. 74720-DEU-001

[BAR CODE AREA]

[CHANELLE BRAND LOGO]
{END - BACK / SIDE PANEL}

{Product Claims to be printed on packaging}

[[Brand Name] provides easy to use and effective flea, tick, sarcoptic mite, chewing lice and mosquito protection for dogs and puppies 8 weeks of age or older]

[Mosquitoes]

- [Controls mosquitoes within 24 hours for up to [7 days][1 week]] [and within 48 hours for up to [28 days][one month]]
- [Controls mosquitoes]

[Adult Fleas]

- [Controls adult fleas for up to [3 months][90 days]]
- [Controls adult Fleas Up to [4 weeks] [1 month] [30 days]!]
- [Dogs with a high risk for flea reinfestation should be retreated once monthly]
- [Controls adult fleas which may cause flea [allergy dermatitis][,] [and] [bite anemia].]
- [Controls newly emerged adult fleas before they lay eggs]

[Ticks]

- [Controls ticks including those that may transmit Lyme disease]
- [Controls Ticks for Up to [4 weeks] [1 month] [30 days]!]
- [Controls Deer Ticks (that may carry Lyme disease) for up to [4 weeks] [1 month] [30 days]]
- [Controls Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
- [Controls [brown dog ticks][,] [(*Rhipicephalus sanguineus*)][,] [American dog ticks][,] [and] [lone star ticks][.] [for up to [4 weeks] [1 month] [30 days].]]
- [Controls [Brown][,] [American][,] [and] [Lone Star] Dog Ticks[.] [for up to [4 weeks] [1 month] [30 days].]]
- [Controls all stages (larvae, nymph, adult) of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)]
- [Controls American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[Multiple Infestations]

- [Eliminates chewing lice [and aids in the control of sarcoptic mites]]
- [Quickly halts chewing lice infestations]
- [Helps control sarcoptic mite infestations that cause sarcoptic mange.]
- [Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old and older]
- [Controls fleas, ticks, mosquitoes [&] [and] chewing lice]
- [Controls fleas, ticks, chewing lice, and mosquitoes]
- [Once a month flea, tick, mosquito and chewing lice protection]
- [Four] [4] Way [Action][Controls] [fleas, ticks, mosquitoes, and chewing lice]
- [[4 Week] [1 month] [30 day] [Flea and Tick [&] [and] Application]
- [[Four (4) Week] [1 month] [Flea, Tick, Mosquito and Chewing Lice Protection]
- [Monthly Flea and Tick Treatment]
- [Use [**Brand Name**] once a month to protect from ticks, sarcoptic mites, and chewing lice]
- [Once a month flea, tick, mosquito, and chewing lice protection.]
- [Controls Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]

[All Others]

- [For use on Dogs & Puppies 8 weeks of age or older]
- [Only use on Dogs [7- 22lbs.][23-44 lbs.][45-88 lbs.][89-132 lbs.].
- [Easy to Use]
- [Quick Acting]
- [Long Lasting]
- [Waterproof]
- [Continues to work even after bathing]
- [Apply once every [4 weeks] [1 month] [30 days]!]
- [Protects against reinfestation]
- [Controls fleas which may cause flea allergy dermatitis]
- [Controls newly emerged adult fleas before they lay eggs]
- [Controls all stages larva, nymph, adult) of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)]
- [Controls mosquitoes]
- [Quickly halts chewing lice infestations]
- [Controls mites that may cause sarcoptic mange]
- [Can be used on puppies 8 weeks of age or older]
- [For use on dogs [7-22lbs.] [23-44 lbs.] [45-88 lbs.] [89-132 lbs.]]
- [Contains Fipronil (9.7%)]

{START – BLISTER PACK INFORMATION}



{END – BLISTER PACK INFORMATION}

{START – APPLICATOR INFORMATION}

Front Label	Back Label
<p>{Brand Name} cat prohibition icon Use only on dogs X-Y lbs. Fipronil 9.7% w/w 0.023 fl. oz. (or) 0.045 fl. oz. (or) 0.091 fl. oz. (or) 0.136 fl. oz. {label code}</p>	<p>KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. EPA REG. No. 88051-2 {label code}</p>

{END – APPLICATOR INFORMATION}