


88051-2

8/30/2012

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 <p align="center"><b>ENVIRONMENTAL PROTECTION AGENCY</b></p> <p align="center">Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave N W Washington D C 20460</p>	<p>EPA Registration No</p> <p align="center">88051-2</p>	<p>Date of Issuance</p> <p align="center">August 30 2012</p>
<p align="center"><b>NOTICE OF PESTICIDE</b></p> <p align="center"><input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration</p> <p align="center">(under the Federal Insecticide Fungicide and Rodenticide Act as amended)</p>	<p>Term of Issuance</p> <p align="center"><b>Unconditional</b></p> <hr/> <p>Name of Pesticide Product</p> <p align="center"><b>Zeromil Spot On Solution for Dogs</b></p>	
<p><b>Name and Address of Registrant (include ZIP Code)</b></p> <p><b>Chanelle Pharmaceuticals Manufacturing Ltd c/o Exponent, Inc Center for Chemical Regulation and Food Safety 1150 Connecticut Avenue NW, Suite 1100 Washington, DC 20036</b></p> <p><b>Note</b> 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</p>		
<p>On the basis of information furnished by the registrant the above named pesticide is hereby registered under the Federal Insecticide Fungicide and Rodenticide Act</p> <p>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</p> <p>This action is taken under the authority of section 3(c)(5) of the Federal Insecticide Fungicide and Rodenticide Act as amended Registration under this section does not eliminate the need for continual reassessment of pesticides EPA may require submission of data at any time to maintain the registration of your product</p> <p align="center"><b>Terms of Registration</b></p> <p>1 EPA has registered the product listed above provided that the following change is made to the label before you release the product for shipment</p> <p>a Revise the EPA Registration Number to read EPA Registration No 88051 2</p> <p>b The Net Contents in all locations must be displayed in accordance with the description identified in the Labeling Consistency Committee s clarification This information may be located at the following Agency web site under miscellaneous <a href="http://www.epa.gov/opp00001/regulating/labels/label_review_faq.htm#miscellaneous">http://www.epa.gov/opp00001/regulating/labels/label_review_faq.htm#miscellaneous</a> Regarding listing net contents Net weight or contents must be stated on a pesticide label in accordance with FIFRA (2)(q)(2)(C)(iii) and 40 CFR 156.10(a)(1)(iii) EPA interpretation of the statutory and regulatory requirements is that the label must state the total weight for the entire contents as sold and distributed In</p>		
<p>Signature of Approving Official</p> <p align="center">Refer to Page 3</p> <p>Richard J Gebken Product Manager (10) Registration Division Insecticide Branch</p>	<p>Date</p> <p align="center">August 30 2012</p>	

addition the label may indicate the net weight and quantity of individual units within the carton For example Net Weight 6.25 lbs (20 5oz packets) For additional information regarding the Net Weight/Contents statement please reference Chapter 17 of the Label Review Manual at [http://www.epa.gov/oppfead1/labeling/lrm/chap\\_17.htm](http://www.epa.gov/oppfead1/labeling/lrm/chap_17.htm)

- c Under the brand name Zeronil Spot On Solution for Dogs and any other alternate brand name add the following statement **For use ONLY on DOGS 12 weeks and older** The word DOG the word dog must be the same size as the brand name
- d **Pictures** Chanelle Pharmaceuticals Manufacturing Ltd must place large clear pictures of the appropriate species on the front panel

2 This registration is **time limited and expires two years from the date this product is first released for shipment** You must provide the Agency with a projected release for shipment date in writing within 30 days of the date of this Notice of Registration The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing

3 Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e. no alternate formulations or minor formulation amendments will be submitted and/or approved for this product except to allow for alternate sources of any individual inert ingredient)

4 You must submit the following data within the timeframe described below Within sixteen (16) months of the date on this Notice of Registration provide to the Agency acceptable data packages for Guideline Studies OPPTS 830 6320 (Corrosion Characteristics) and OPPTS 830 6317 (Storage Stability)

5 You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1 2012 The quarterly reports are due two months after the end of each quarter Please flag any Confidential Business Information (CBI) as such Enhanced incident reporting should be submitted to the Product Manager Quarterly sales information should be submitted to the Registration Division Immediate Office (attn Kimberly Nesci)

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

- EPA Registration Number
- Product name (brand name)
- Lot#
- Where purchased internet store Veterinarian
- Active Ingredient(s)
- Weight range for product
- Date on which incident occurred (mm/dd/yyyy)
- State in which the incident occurred (standard 2 letter abbreviation)
- Registrant case #
- Species dog cat other (specify)
- Breed (as reported by pet owner)
- Age months or years
- Sex M F or neutered
- Weight pounds
- Primary Route of Exposure dermal oral other animal inhalation other
- Body System neurological dermatological GI respiratory ocular other Major signs noted
- Time to Onset (hours days)
- Treated by veterinarian yes or no
- First time product used yes or no
- Misuse use on incorrect species overdose too frequent dosing other (describe)
- Any known precondition
- EPA Severity Code death major moderate minor
- Outcome died recovered still treated unknown

6 Along with the enhanced incident reporting you must submit an analysis of all incidents seen to include the following details

- a All minor dermal and ocular irritation reports
- b Summary table for dogs showing number of incidents of each severity code for each route of exposure Each incident should only be reported once If one incident has several routes of exposure the order should be ocular > oral > dermal In other words an incident with both oral and dermal exposure would be

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reported as oral exposure and an incident with both ocular and oral exposure would be reported as ocular exposure

c A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each

severity code for each route of exposure

d Summary table for dogs and table for dogs showing number of incidents that are believed due to secondary exposure (e.g. multi pet households)

e A summary table for s showing number of incidents for each severity code for these age ranges <3 months 3-6 months 6-9 months 9-12 months 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 10 yr 11 yr 12 yr 13 yr 14 yr 15 yr >15 yr

f A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label

g A summary table for dog weight showing number of incidents for each product weight range This table should show number of incidents in dogs weighing less than that product weight range number of incidents in dogs in lower half of weight range number of incidents in dogs in upper half of weight range and dogs weighing more than the product weight range

h Table showing number of incidents for each dog breed

i Table showing number of incidents in dog for each clinical sign

j Table showing number of incidents in dog for each organ system

k Report aggregate incidents but do not combine moderate and minor incidents

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

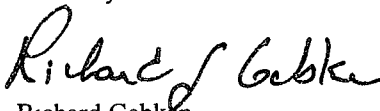
8 Chanelle Pharmaceuticals Manufacturing Ltd must adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot On Mitigation Plan* available at the following internet site within 60 days following the date of this Notice of Registration [http://www.epa.gov/pesticides/health/spot\\_on\\_meetings.html](http://www.epa.gov/pesticides/health/spot_on_meetings.html)

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

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

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

Sincerely



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

Enclosures

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[ ] – Denotes optional statements and/or images

{Master Label}

# Zeronil Spot-On Solution for Dogs

## USE ONLY ON DOGS AND PUPPIES OVER 12WEEKS OF AGE

[[Full 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 ]

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

[[Full Brand Name] for dogs [&] [and] puppies 12 weeks or older Easy to use spot treatment for quick-acting, long lasting control of fleas, ticks, sarcoptic mites, chewing lice and mosquitoes ]

[[Full Brand Name] provides easy to use and effective flea tick, sarcoptic mites chewing lice and mosquito control for dogs and puppies over 12weeks of age ]

[For use ONLY on dogs [Up to 22 lbs ][23-44 lbs ][45-88 lbs ][89-132 lbs ] [over 12 weeks of age] ]

- [For use on Dogs & Puppies 12 weeks or older and] [up to 22lbs ]
- [For use on Dogs 23-44 lbs ]
- [For use on Dogs 45-88 lbs ]
- [For use on Dogs 89-132 lbs ]

ACCEPTED  
With COMMENTS  
In EPA Letter Dated  
*August 30, 2012*  
Under the Federal Insecticide, Fungicide  
and Rodenticide Act, As amended, for the  
pesticide Registered under EPA Reg No  
88051-2

ACTIVE INGREDIENT  
Fipronil  
OTHER INGREDIENT  
TOTAL

9.70%  
90.30 %  
100.00%

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

### 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

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**HAZARDS TO DOMESTIC ANIMALS** For external use only Do not use on puppies under 12weeks of age 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 or aged dogs

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

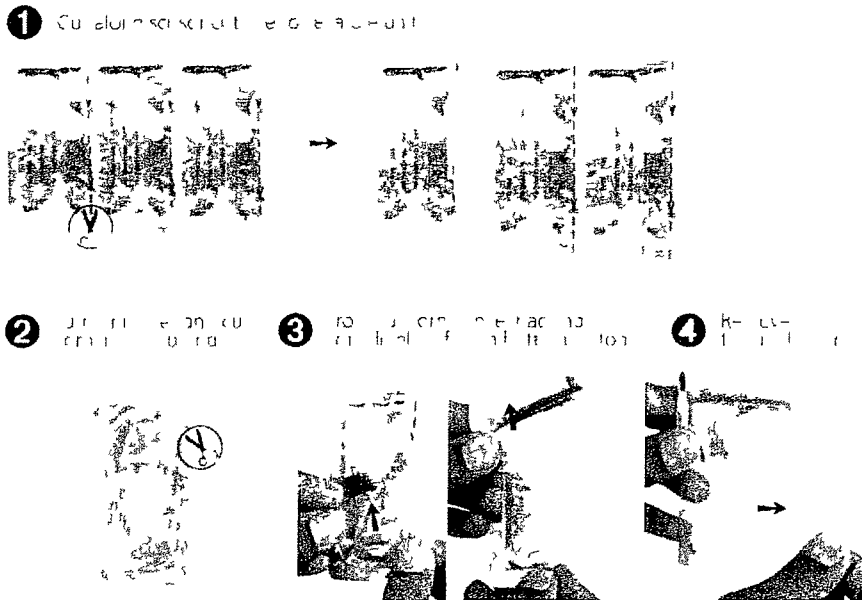
**DIRECTIONS FOR USE**

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**

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 on dogs and puppies (12weeks or older) as follows

**DIRECTIONS FOR OPENING PACKAGING**



**DIRECTIONS FOR APPLICATION OF PRODUCT**

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

**Use Only one applicator per treatment**

[Full 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, [Full Brand Name] will completely control flea, tick, mosquito, and chewing lice infestations

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

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

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

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

**Mosquitoes** – **[Full 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]

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

**For Dogs Weighing up to 22 lbs [which includes small dogs and puppies, 12 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

**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

**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

**For Dogs Weighing 89 - 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

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**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 4 (30 Aug 2012)**

Distributed by  
Chanelle Pharmaceuticals Manufacturing Ltd  
Dublin Road  
Loughrea Co , Galway  
Ireland  
EPA Reg No 88051-NEW  
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 12 WEEKS OF AGE**

[[Full Brand Name] provides an easy to use and effective flea, tick, sarcoptic mite chewing lice and mosquito protection for dogs and puppies 12 weeks 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 12 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 [**Full 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 12 weeks of age or older]
- [Only use on Dogs [up to 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 12weeks or older]
- [For use on dogs [up to 22lbs ] [23-44 lbs ] [45-88 lbs ] [89-132 lbs ]]
- [Contains Fipronil (9.7%)]

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**{START - FRONT PANEL OF PACKAGING}**

[[Full Brand Name] for dogs [&] [and] puppies 12 weeks 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** [Three] [3] 0 023 fl oz (0 67 mL) applicators  
[Three] [3] 0 045 fl oz (1 34 mL) applicators  
[Three] [3] 0 091 fl oz (2 68 mL) applicators  
[Three] [3] 0 136 fl oz (4 02 mL) applicators

**{END - FRONT PANEL OF PACKAGING}**

**{START – BACK/SIDE PANEL OF PACKAGING}**

[[Full 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 [up to 22lbs ][23-44 lbs ][45-88 lbs ][89-132 lbs ] over 12 weeks of age ]

[Brand Name]

**READ ENTIRE LABEL BEFORE EACH USE  
USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE**

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

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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 12 weeks of age 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 or aged dogs

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

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[[Full Brand Name] provides easy to use and effective flea, tick, sarcoptic mange mite, chewing lice and mosquito protection for dogs and puppies 12weeks or older]

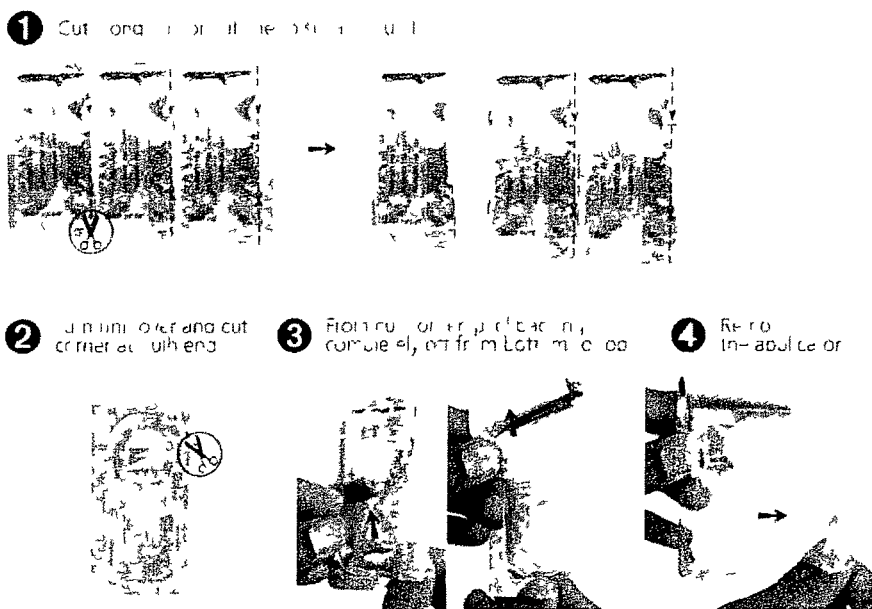
### DIRECTIONS FOR USE

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**

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 on dogs and puppies (12 weeks or older) as follows

### DIRECTIONS FOR OPENING PACKAGING



### DIRECTIONS FOR APPLICATION OF PRODUCT

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

**Use only one applicator per treatment**

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**FREQUENCY OF APPLICATION**

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

**Fleas** – Studies show that [Full Brand Name] controls adult fleas for up to [3][three] months Although [Full Brand Name] protects dogs from fleas for up to [3][three] months, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis or flea bite anemia, a once a month application may be necessary

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

**Mites** - [Full 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** – [Full 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]

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

**For Dogs Weighing up to 22 lbs [which includes small dogs and puppies, 12 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

**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

**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

**For Dogs Weighing 89 - 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

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**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.



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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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Ireland  
EPA Reg No 88051-NEW  
EPA Est No 74720-DEU 001

[BAR CODE AREA]

[CHANELLE BRAND LOGO]

**{END - BACK / SIDE PANEL}**

**{Product Claims to be printed on packaging}**

[[Full Brand Name] provides easy to use and effective flea, tick, sarcoptic mite, chewing lice and mosquito protection for dogs and puppies 12 weeks 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 12 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 [**Full 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 12 weeks of age or older]
- [Only use on Dogs [up to 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]

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- [Quickly halts chewing lice infestations]
- [Controls mites that may cause sarcoptic mange]
- [Can be used on puppies 12weeks or older]
- [For use on dogs [up to 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><b>{Brand Name}</b>            [Use only on dogs [up to X][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><b>KEEP OUT OF REACH OF CHILDREN</b>  <b>CAUTION</b> Read directions and            precautions before using            EPA REG No 88051-NEW {label code}</p>

**{ END – APPLICATOR INFORMATION}**