U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460	EPA Reg. Number: 70585-12	Date of Issuance: 2/6/16
NOTICE OF PESTICIDE: <u>X</u> Registration Reregistration	Term of Issuance: Conditional, Time-Limited Expires: 02/06/2018	
(under FIFRA, as amended)	Name of Pesticide Product: Parastar For Dogs	
Name and Address of Registrant (include ZIP Code): Leanne Pruett Pyxis Regulatory Consulting, Inc. Agent for Novartis Animal Health US, Inc. 4110 136 th St. CT NW Gig Harbor, WA 98322		
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:		
 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: Kable Bo Davis, Product Manager 3 Invertebrate & Vertebrate Branch 1	Date: 2/6/16	
Registration Division (7505P) EPA Form 8570-6		

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- 2. This registration is time-limited and expires 02/06/2018.
- 3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. 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 with separate column for each sign, using standard terminology
 - 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
- 4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - 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 reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

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- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs 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.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- 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, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

- 5. You are required to comply with the data requirements described in the DCI Orders identified below:
 - a. Fipronil GDCI-129121-1305
 - b. Fipronil GDCI-129121-152

You must comply with all of the data requirements within the established deadlines. If you have questions about the DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <u>http://www.epa.gov/oppsrrd1/contacts_prd.htm</u>

- 6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 70585-12."
- 7. 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

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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 01/15/2016

If you have any questions, you may contact Julie Breeden at 703-347-0511 or via email at <u>Breeden.Julie@epa.gov</u>.

Enclosure

[Optional text appears in brackets -the final label may include some or all of the optional text on front, back, side, or inside label panels]



[(fipronil)]

ACCEPTED 02/06/2016

70585-12

Apply only to puppies more than 8 weeks old and over [4][23][45][89] lbs. [[*alternate language*]Apply only to puppies 8 weeks or older and over [4][23][45][89] lbs.] [4-22 lbs] [23-44 lbs] [45-88 lbs] [89-132 lbs]

[Mosquitoes]

• [[Kills mosquitoes] [within 24 hours] [within 24 hours for up to the first 7 days after treatment, and within 48 hours for up to 28 days]]

[Adult Fleas]

- [[Kills [adult] fleas [for up to [three] [3] months] [!]]
- [Kills newly emerged adult fleas before they lay eggs]
- [Kills fleas [, a source of flea allergy dermatitis] [, flea bite anemia]]
- [Kills fleas [for] up to [4 weeks] [1 month] [30 days] [!]]
- [If dog is a high risk for flea reinfestation apply once-a-month application]

[Ticks]

- [Kills ticks, including those that may transmit Lyme disease]
- [Kills ticks for up to [[4] [four] weeks] [1 month] [30 days]!]
- [Kills deer ticks [[that may transmit Lyme disease,] for up to [[4] [four] weeks] [l month] [30 days]]
- [Kills ticks (including deer ticks) for up to [[4] [four] weeks] [l month] [30 days]]
- [Kills [brown dog ticks], [American dog ticks,] [[and] lone star ticks]
- [Kills ticks]
- [Kills [brown], [American dog,] [and] [lone star,] ticks [(*Rhipicephalus sanguineus*)] for up to [[4] [four] weeks] [1 month] [30 days]]
- [Kills American dog ticks [(*Dermacentor variabilis*)] for up to [[4] [four] weeks] [1 month] [30 days]!]

[Multiple Infestations]

- [Kills [chewing lice] [and] [[C][c]ontrols mites that may cause sarcoptic mange]
- [[Flea] [&] [and] [tick] control only for dogs [&] [and] [puppies 8 weeks old and older] [more than 8 weeks old]]
- [Kills [fleas], [ticks] [&] [and] [chewing lice] [&] [and] mosquitoes]
- [Kills [fleas] [,] [&] [and] [ticks] [and mosquitoes]
- [Kills [fleas], [ticks] [,] [&] [and] [chewing lice] [and] [mosquitoes]]
- [Kills [fleas], [ticks], [mosquitoes] and [chewing lice]]

- [Monthly [flea], [tick], [mosquito], and [chewing lice] [treatment]]
- [[Four] [Three] [4] [3] [-]way [action] [control] [kills [fleas], [ticks] [, mosquitoes,], [chewing lice]]
- [[4-Week] [l-month] [30-day] [flea] [and] [&] [tick] treatment]
- [[Four [4] [-] Week] [l-month] [flea], [tick], [mosquito], [and] [&] [chewing lice] control]
- [Kills [fleas] and [ticks] for up to [[4] [four] weeks] [1 month] [30 days]!]
- [Once-a-month [flea] and [tick] treatment]
- [Use [Parastar[®] [For Dogs]] monthly to control [ticks] and [chewing lice]]
- [Use [Parastar[®] [For Dogs]] monthly to control [fleas], [ticks] and [chewing lice]]
- [Monthly [flea], [tick], [mosquito], [and] [&] [chewing] [lice].]
- [Parastar[®] [For Dogs]] provides convenient and effective [flea], [tick] [,] [&] [and] [chewing lice] [and mosquito] control only for dogs and puppies 8 weeks and older.]

All Others

- [For use only on dogs and puppies [more than 8 weeks old]]
- [For use only on dogs and puppies [8 weeks old and older and weighing 4 [to [-] 22 lbs.]
- [For use only on dogs weighing [4 [to] [-] 22 lbs], [23 [-] [to] 44 lbs], [45[-] [to] 88 lbs], [89 [-] [to] 132 lbs]
- [Fast-acting] [Fast acting]
- [Long-lasting] [Long lasting]
- [Prevents [flea] reinfestation of listed pests for [1 month] [4 weeks]]
- [Stops and prevents infestation of listed pests for [4 weeks][1 month]
- [Stops existing infestation and prevents establishment of additional infestation of listed pests]
- [Convenient spot treatment]
- [Once-a-month treatment]
- [A once monthly application for chewing lice.]
- [Fast action against chewing lice infestations]
- [Controls mites that may cause sarcoptic mange]
- [One Application] [Two Applications] [Three Applications] [Four Applications] [Five Applications] [Six Applications] [Twelve Applications] [Twenty-Four Applications] and/or [1-month supply] [2-month supply] [3-month supply] [4-month supply] [5-month supply] [6-month supply] [12-month supply] [24-month supply] or [4- week supply] [8-week supply] [12-week supply] [16-week supply] [20-week supply] [24-week supply] [48-week supply] [52-week supply] [104-week supply] or [[1] [2] [3] [4] [5] [6] [12] [24] applications]
- [Best if used year round!]
- [4[-]week dose[!]] [in Child Resistant Packaging]
- [1[-]month dose[!]] [in Child Resistant Packaging]
- [30[-]day dose[!]] [in Child Resistant Packaging]
- [A fipronil product]
- [fipronil (9.7%)]
- [Contains fipronil[,] [-] the active ingredient [used] in Frontline® Top Spot®*
- [*Parastar[®] [For Dogs] is not manufactured by or distributed by Merial. Frontline[®] Top Spot[®] is a registered trademark of Merial.]
- [Specially formulated for dogs and puppies older than 8 weeks]

- [Fast-acting, long-lasting that's also waterproof.]
- [[1] [2] [3] [4] [5] [6] [12] [24] Easy-to-Use Applications!] [in Child Resistant Packaging]
- [Easy-to-use [application]]
- [[Free] calendar stickers inside!]
- [[Free] calendar stickers inside]
- [Apply once every [4 weeks] [month] [30 days]!]
- [Waterproof]
- [Dogs can be bathed 24 hours after [application] [treatment] [Parastar[®] [For Dogs]] is applied]]
- [Can be used on breeding, pregnant and lactating [dogs] [bitches] [female dogs]]
- [[Free with purchase] [Free inside] Monthly Application Reminder [Magnet] [clip]
- [card] [inside]]
- [Can be used only on puppies [more than 8 weeks of age]
- [Can be used only on puppies [8 weeks of age and older]
- [Monthly application reminder card inside]
- [Optional graphics: Images of the different kinds of bugs killed with a line drawn through]
- [Dogs [N][n]eed [A][a]dventure[!]]
- [Adventure [P][p]ack]
- [Tick and Flea [P][p]rotection for [A[[a]dventurous [D][d]ogs]
- [Protection [P][p]ack]
- [Protection from [H][h]ead to [T][t]oe]
- [This [adventure][protection] pack contains a single dose of Parastar for Dogs along with other valuable offers [to help ensure that your dog is always [ready for adventure][covered].]

[For use only on Dogs & Puppies 8 weeks or older and weighing 4 [to] [-]22 lbs.] [For use only on Dogs weighing 23[-] [to] 44 lbs.] [For use only on Dogs weighing 45[-] [to] 88 lbs.] [For use only on Dogs weighing 89[-] [to] 132 lbs.]

EPA Reg. No. 70585-RE EPA Establishment No.

ACTIVE INGREDIENTS:

Fipronil	9.7 %
INERT INGREDIENTS:	90.3%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

See [Back][or][Side][or][Interior Panel][Label Panel[s] for Additional Precautionary Statements [and First Aid Statements]

NET CONTENTS:

[Contains] [1] [One] [2] [Two] [Three] [3] [4] [Four] [5] [Five] [6] [Six] [12] [Twelve] [24]
[Twenty-Four] [-] 0.023 fl oz (0.67 ml) applicators
[Contains] [1] [One] [2] [Two] [Three] [3] [4] [Four] [5] [Five] [6] [Six] [12] [Twelve] [24]
[Twenty-Four] [-] 0.045 fl oz (1.34 ml) applicators
[Contains] [1] [One] [2] [Two] [Three] [3] [4] [Four] [5] [Five] [6] [Six] [12] [Twelve] [24]
[Twenty-Four] [-] 0.091 fl oz (2.68 ml) applicators
[Contains] [1] [One] [2] [Two] [Three] [3] [4] [Four] [5] [Five] [6] [Six] [12] [Twelve] [24]
[Twenty-Four] [-] 0.136 fl oz (4.02 ml) applicators

Parastar[®] [For Dogs] contains fipronil to effectively kill fleas and ticks [[(]including those that may transmit Lyme Disease[)]]. [This product features a sustained-release formula for fast-acting [and long-lasting] control of [fleas], [ticks], [mosquitoes] and [chewing lice] [for up to [1 month] [4 weeks] on dogs].

[Back / Side Panel of Outer Packaging]

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.

[Parastar[®] For Dogs provides [four-] [three-] way protection that kills [fleas], [ticks], [mosquitoes] and [chewing lice]. Controls mites that may cause sarcoptic mange. Kills deer ticks [that transmit Lyme disease]. Kills brown dog ticks, American dog ticks, and lone star ticks. Prevents flea reinfestation.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash 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. Individual sensitivities, while rare, may occur after using any pesticide product. Certain medications can interact with pesticides. Do not treat your dog with more than one topically applied pesticide product at a time. Consult a veterinarian before using on medicated, debilitated or aged dogs. Can be used on breeding, pregnant, or lactating dogs. Consult a veterinarian before using on dogs with known organ dysfunction.

FIRST AID		
If swallowed	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	Hold eye open and rinse slowly and gently with water for 15 to 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	Wash with plenty of soap and water. Get medical attention if irritation	
	persists.	

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-637-0281.

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 ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. 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. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. Do not allow your dog to ingest this product.

Do not apply to puppies less than 8 weeks of age. Do not apply to dogs or puppies weighing less than [4][23][45][89] lbs. For use only on dogs [[&] [and] puppies] [weighing 4 [-] [to] 22 lbs] [weighing 23 [-] [to] 44 lbs.] [45 [-] [to] 88 lbs.] [weighing 89 [-] [to] 132 lbs.] Do not split one tube between dogs. [[*alternate language*]Do not use multiple tubes on one dog.] Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. [Do not double-dose dogs weighing greater than 132 lbs.]





Side Effects

Monitor your dog after application. [Some dogs may experience temporary startle effects when product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching, or other signs of discomfort. If signs of a sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call Novartis Animal Health at 1-800-637-0281. If your dog has an unusual reaction to the initial application, consult a veterinarian before

repeating treatment. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur immediately feed your dog and continue to monitor your dog for the next 24 hours.



[{Outer Packaging or Interior Carton Panel}]

How to open: Remove product [tube[s]] [vial[s]] from the package. [Separate one tube from the others.] Hold the [tube] [vial] with notched end pointing up and away from the face and body₇. Use scissors to cut off the narrow end at the notches along the line.

How to apply: While holding the dog with one hand, use the other hand to apply the solution. Invert the [tube] [vial] and use the open end to part the dog's hair. Apply contents of one [tube] [vial] of Parastar[®] [For Dogs] [as a spot to the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail]. Hold the dog for a few seconds to give the solution time to be absorbed into the dog's coat. When finished, wrap the [tube] [vial] in paper and put into the trash. Only one applicator per treatment is needed. Repeat application may be made if necessary, but do not apply more often than once every 30 days.

[Optional drawings of application process that may or may not appear on finished label]

FREQUENCY OF APPLICATION

Use Parastar[®] [For Dogs] monthly for control of [flea], [tick] [and] [chewing lice] [and mosquito] infestations. [Studies show that] Parastar[®] [For Dogs] kills fleas for up to three months. If your dog is at high risk for flea reinfestation [, or in a highly infested environment], apply monthly. Apply monthly to control [ticks], [mosquitoes] and [chewing lice]. [Parastar[®] [For Dogs] kills mosquitoes within 24 hours for up to the first 7 days after treatment, then within 48 hours for up to 28 days.] Parastar[®] [For Dogs] remains effective, after water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. [Dogs can be bathed 24 hours after treatment] Do not reapply for 30 days.

For use only on Dogs Weighing [4] [to] [-] 22 lbs. [including small dogs and puppies, 8 weeks or older]:

{For cartons containing .67 ml (0.023 fl oz) applicator tubes)

Apply one tube [0.023 fl. oz. [(0.67 mL)]] [(0.67 mL) (0.023 fl. oz.)] [0.67 mL [(0.023 fl. oz.)]] [from the back of the neck to a point midway between the neck and tail.] [as a spot on the dog's back between the shoulder blades.]

For use only on Dogs Weighing 23 [-] [to] 44 lbs.

{For cartons containing 1.34 mL (0.045 fl. oz.) applicator tube)

Apply one tube [0.045 fl. oz. [(1.34 mL)]] [(1.34 mL) (0.045 fl. oz.)] [1.34 ml [(0.045 fl. oz.)]] [from the back of the neck to a point midway between the neck and tail.] [as a spot on the dog's back between the shoulder blades.]

For use only on Dogs Weighing 45[-] [to] 88 lbs.

{For cartons containing 2.68 mL (0.091 fl. oz.) applicator tube)

Apply one tube [0.091 fl. oz. [(2.68 mL)]] [(2.68 mL) (0.091 fl. oz.)] [2.68 mL [(0.091 fl. oz.)]] [from the back of the neck to a point midway between the neck and tail.] [as a spot on the dog's back between the shoulder blades.]

For use only on Dogs Weighing 89[-] [to] 132 lbs

For cartons containing 4.02 mL (0.136 fl. oz.) applicator tube)

Apply one tube [0.136 fl. oz. [(4.02 mL)]] [(4.02 mL) (0.136 fl. oz.)] [4.02 mL [(0.136 fl. oz.)]] [from the back of the neck to a point midway between the neck and tail.] [as a spot on the dog's back between the shoulder blades.]

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: Non-refillable container. Do not reuse or refill this container. If empty: Place in the 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.

[Optional Exterior or Interior package copy]

WARRANTY

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of NOVARTIS ANIMAL HEALTH US, Inc. (NAHUS) or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold NAHUS and Seller harmless for any claims relating to such factors.

NAHUS warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or NAHUS, and Buyer and User assume the risk of any such use. TO THE EXTENT

CONSISTENT WITH APPLICABLE LAW, NAHUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with State law, in no event shall NAHUS or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF NAHUS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF NAHUS OR SELLER, THE REPLACEMENT OF THE PRODUCT.

[If you have questions or comments about this product, please write to: Novartis Animal Health US, Inc., (address).]

For Technical Information, call: 1-800-637-0281 [hours of service] [Made in USA]

[Distributed by] [Manufactured for][Available exclusively from]: Novartis Animal Health US, Inc. 3200 Northline Avenue, Suite 300 Greensboro, NC 27408

[BAR CODE AREA]

EPA Reg. No. 70585-RE EPA Est. NO. XXXXX-XXXX

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

How to Open:

1. Remove product [tube[s]] [vial[s]] from the package.

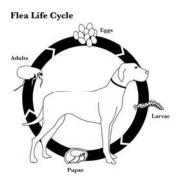
2. [Separate one [tube] [vial] from the others.] Hold the [tube] [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert [tube] [vial] over dog and use open end to part dog's hair.

2. Squeeze [tube] [vial] firmly to apply all of the solution to the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Example Flea life cycle diagram – actual may differ slightly]



[Look at the Label (Look at the Label icon)

[[Easy] [6] [Six-] [Step] [Parastar[®] [For Dogs]] [Spot-on] [Squeeze-On] Checklist

- 1. Read the label completely and follow directions.
- 2. Weigh your dog.
- 3. Do NOT use dog products on cats.
- 4. Do NOT treat with more than one pesticide product at a time.
- 5. Separate animals after treatment to avoid chance of ingestion.
- 6. Do NOT split tubes between dogs.]

[Parastar[®] [For Dogs]]

[Monthly reminder card] [Fill out this reminder card with your dog's name and the date each treatment should be given to your dog as a reminder to reapply [Parastar[®] [For Dogs]] every 30 days.] [optional graphics that may or may not appear on label] [Apply [Parastar[®] [For Dogs]] monthly.] [Dog's Name (Empty blank for owner to fill in name)] [First [dose] [Treatment] (Empty blank for owner to fill in date)] [Second [dose] [Treatment] (Empty blank for owner to fill in date)] [Third [dose] [Treatment] (Empty blank for owner to fill in date)] [Fourth [dose] [Treatment] (Empty blank for owner to fill in date)] [Fifth [dose] [Treatment] (Empty blank for owner to fill in date)] [Sixth [dose] [Treatment] (Empty blank for owner to fill in date)] [Seventh [dose] [Treatment] (Empty blank for owner to fill in date)] [Eighth [dose] [Treatment] (Empty blank for owner to fill in date)] [Ninth [dose] [Treatment] (Empty blank for owner to fill in date)] [Tenth [dose] [Treatment] (Empty blank for owner to fill in date)] [Eleventh [dose] [Treatment] (Empty blank for owner to fill in date)] [Twelfth [dose] [Treatment] (Empty blank for owner to fill in date)]

[Visit [web-address] to download a free convenient application for your smartphone for an electronic calendar reminder]

[Visit [web-address] to download a convenient electronic calendar reminder]

[calendar stickers with Parastar[®] [For Dogs]] [[1] [2] [3] [4] [5] [6] [12] [24] -month] [application tracker] [Apply Parastar[®] [For Dogs] monthly. Place stickers on your calendar as a reminder to reapply [Parastar[®] [For Dogs]] in 30 days.] [It's time for Parastar[®] [For Dogs]] [!]] [Enclosed for your convenience [is] [are] [1] [2] [3] [4] [5] [6] [12] [24] [one] [two] [three] [four] [five] [six] [twelve] [twenty-four] sticker[s].] [Place stickers on your calendar every 30 day from initial treatment as a reminder to reapply Parastar[®] [For Dogs] every 30 days.]

[Optional Example graphics for calendar stickers, reminder cards, and/or magnets.]

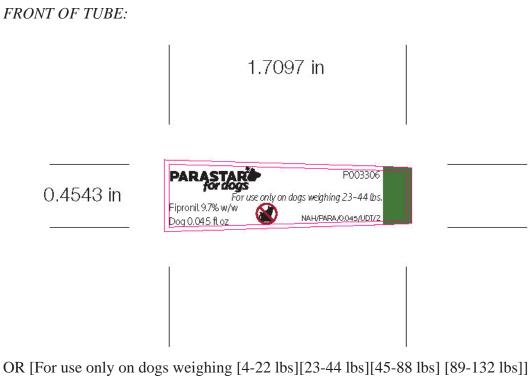


[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply Parastar[®] [For Dogs]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

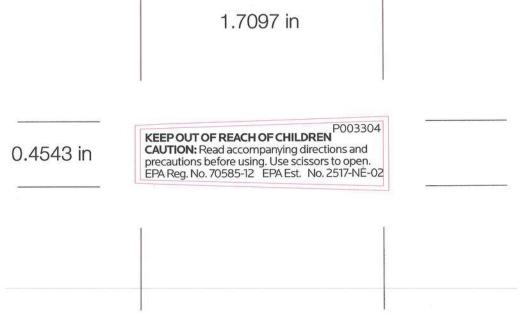
{END - OPTIONAL EXTERIOR OR INTERIOR PANEL PACKAGE COPY}

BEGIN TUBE LABEL



OR [[.023] [.045] [.091] [.136] fl. oz.] [[.67] [1.34] [2.68] [4.02] mL]

BACK OF TUBE:



END TUBE LABEL

[OPTIONAL GRAPHICS FOR EXTERIOR OR INTERIOR PANEL PACKAGE:

Example pictograms that may or may not be found on the printed label]







EPA[approval date]