



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

EPA Reg. Number:

70585-13

Date of Issuance:

2/6/16

NOTICE OF PESTICIDE:

Registration  
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited  
 Expires: 02/06/2018

Name of Pesticide Product:

Parastar Plus 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<sup>th</sup> 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:

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

Signature of Approving Official:

Kable Bo Davis, Product Manager 3  
 Invertebrate & Vertebrate Branch 1  
 Registration Division (7505P)

Date:

2/6/16

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.

- 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 Order identified below:
  - a. Fipronil GDCI-129121-1305
  - b. Fipronil GDCI-129121-152
  - c. Cyphenothrin GDCI-129013-1102
  - d. Cyphenothrin GDCI-129013-877

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: [http://www.epa.gov/oppsrrd1/contacts\\_prd.htm](http://www.epa.gov/oppsrrd1/contacts_prd.htm)

6. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, “EPA Reg. No. 70585-13.”
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 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

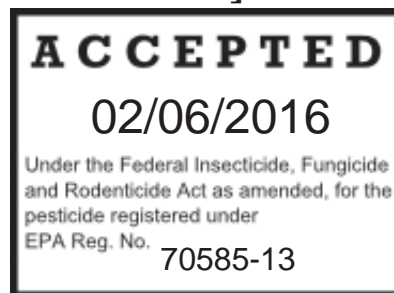
If you have any questions, you may contact Julie Breeden at 703-347-0511 or via email at [Breedden.Julie@epa.gov](mailto:Breedden.Julie@epa.gov).

Enclosure

[ ] - Denotes Optional Statements and/or Images that May be Used on Front, Back or Side Label Panels

## [FRONT CARTON LABEL - MASTER LABEL COPY STARTS]

**Parastar<sup>®</sup> Plus**  
**For Dogs**  
[(fipronil/cyphenothrin)]



Apply only to puppies over 12 weeks old and over [4] [23][45][89] lbs.

[[*alternate language*] Apply only to puppies 12 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 for up to the first 7 days after application, and within 48 hours for up to 28 days]
- [• [Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]
- [Kills mosquitoes]

### [Chewing Lice]

- [• Kills chewing lice]
- [• Rapidly eliminates infestations of chewing lice]

### [Fleas]

- [• [Quickly] [K][k]ills fleas]
- [• Kills fleas fast]
- [•Kills adult fleas] [in as little as 1 hour] [!] [for up to three months]
- [•Kills newly emerged adult fleas (starts killing in as little as 1 hour) before they lay eggs]
- [•Kills fleas [in as little as 1 hour], which may be a source of flea allergy dermatitis] [or, flea bite anemia]
- [•Kills fleas [in as little as 1 hour]]
- [• Kills fleas [in as little as 1 hour] Up to [4 weeks] [1 month] [30 days]!]
- [•If dog is at high risk of flea reinfestation, apply once a month]
- [•Starts [[ killing] [to kill]] fleas in [as little as] [just] [5] [15] [minutes] [1 hour] [after application]]

### [Multiple Infestations]

- [•Kills chewing lice] [and] [[C][c]ontrols mites that may cause sarcoptic mange]
- [• [Kills chewing lice and] [A][a]ids in control of mites that cause sarcoptic mange]
- [•Controls mites, a leading cause of sarcoptic mange]
- [•Starts [[killing] [to kill]] fleas and ticks in [just] [5] [15] [minutes] [1 hour] [after application]]

- [Quickly] [K][k]ills fleas and ticks]
- Flea [&] [and] Tick Control only for Dogs [&] [and] Puppies 12 weeks old and older] [more than 12 weeks of age]
- Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)] [and] chewing lice [&] [and] [mosquitoes]
- Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], [and kills Mosquitoes], [and kills chewing lice]]
- Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], and kills chewing lice [&] [and] [mosquitoes]]
- Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], [mosquitoes,] and chewing lice]]
- Kills [and] Fleas, Ticks, [and kills chewing lice] [and] [mosquitoes]
- Monthly flea, tick, mosquito, and chewing lice application]
- Kills Fleas (starts killing in as little as 1 hour), Ticks (starts killing in as little as 1 hour), mosquitoes, and lice]]
- [4 Week] [1 month] [30 day] [Flea and Tick Application]
- [Four (4) Week] [1 month] [30 day] [Flea, Tick, Mosquito and Chewing Lice Application]
- Kills Fleas (starts killing in as little as 1 hour) and Ticks (starts killing in as little as 1 hour) for up to [4 weeks] [1 month] [30 days]!] [Once A Month Flea and Tick Application]
- Use Parastar<sup>®</sup> Plus [For Dogs] monthly to control Ticks (starts killing in as little as 1 hour) and chewing lice]
- Monthly flea, tick, mosquito, and chewing lice protection.]
- Flea & Tick Control only for Dogs & Puppies 12 weeks old and older] [more than 12 weeks of age]
- Kills Fleas [(starts killing in as little as 1 hour), Ticks [(starts killing in as little as 1 hour)], and kills chewing lice & mosquitoes]
- Starts [[killing] [to kill]] fleas and ticks in as little as [5][15][minutes] [1 hour] [and continues to kill for a month]]

#### [Ticks]

- [Quickly] Kills Ticks]
- Starts [[killing] [to kill]] ticks in just [5] [15] [minutes] [1 hour] [after application]]
- Kills Ticks (starts killing in as little as 1 hour) including those that may transmit Lyme disease]
- Kills Ticks (starts killing in as little as 1 hour) for Up to [4 weeks] [1 month] [30 days]!] [• Kills] Deer Ticks [that may transmit Lyme Disease,] [ for up to [4 weeks] [1 month] [30 days]]
- Kills Ticks (starts killing in as little as 1 hour)]
- Kills Deer Ticks for up to [4 weeks] [1 month] [30 days]]
- Kills [Brown Dog Ticks], [American Dog Ticks,] [[and] Lone Star Ticks] [(starts killing) in as little as 1 hour] [(*Rhipicephalus sanguineus*)] for up to [4 weeks] [1 month] [30 days]]

- Kills [Brown Dog Ticks], [(*Rhipicephalus sanguineus*)] [(starts killing) in as little as [5] [15] [minutes] [1 hour])] for up to [4 weeks] [1 month] [30 days]]
- Kills American Dog Ticks [and] [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!] ]
- Kills Lone Star Ticks]
- Prevents and control reinfestation of listed pests] [for] [30 days] [1month]]
- Kills ticks that may transmit Lyme disease, Rocky Mountain Spotted fever, ehrlichiosis, babesiosis, bartonellosis, anaplasmosis and hepatolozoonosis]

[All Others]

- For use only on Dogs and Puppies [12 weeks of age or older] [more than 12 weeks of age]] and weighing 4 [to] [-] 22 lbs.
- For use only on Dogs [4 [to] [-] 22 lbs], [23[-][to]44 lbs], [45[-][to]88 lbs], [89[-][to]132 lbs]
- Fast Acting]
- Dogs can be bathed 24 hours after application]
- Long Lasting]
- Remains effective, even after bathing, water immersion, or exposure to sunlight]
- Convenient spot application]
- 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!]
- (ICON Showing 4 Week Protection)]
- 4 Week Dose!] [in Child Resistant Packaging]
- 1 Month Dose!] [in Child Resistant Packaging]
- Fipronil (9.8%) + Cyphenothrin (5.2%)]
- A fipronil and cyphenothrin product]
- [1] [2] [3] [4] [5] [6] [12] [24] [Easy-to-Use] Applications!] [in Child Resistant Packaging]
- Easy to Use [Application]] [in Child Resistant Packaging]
- Specially Formulated for use only on Dogs and Puppies 12 weeks of age or older]
- [Free] Calendar Stickers Inside!]
- [Free] Calendar Stickers Inside]
- Apply once every [4 weeks] [month] [30 days]!]
- Dogs can be bathed 24 hours after squeeze-on is applied]
- Waterproof]
- Can be used only on puppies 12 weeks of age and older][more than 12 weeks of age]
- Monthly application reminder card inside]
- 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]eal to [T][t]oe
- This adventure pack contains a single dose of Parastar Plus for Dogs along with other valuable offers to help ensure that your dog is always ready for adventure.]

**[For use ONLY on Dogs & Puppies] [12 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.]**

**ACTIVE INGREDIENTS:**

Fipronil.....	9.8%
Cyphenothrin.....	5.2%
<b>OTHER INGREDIENTS:.....</b>	<b>85.0%</b>
<b>TOTAL: .....</b>	<b>100.0%</b>

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See [Back][or][Side] [Label Panel[s] [or] [insert] for full Directions for Use, First Aid and Precautionary 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





[Front Panel Cat Prohibition Icons – 1.5 x 1.5 cm]

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



**[FRONT CARTON LABEL - MASTER LABEL COPY ENDS]**

## **[BACK CARTON LABEL - MASTER LABEL STARTS]**

**[For use only on Dogs & Puppies] [12 weeks of age 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.]**

[Parastar<sup>®</sup> Plus For Dogs contains Fipronil and Cyphenothrin to effectively kill [in as little as 1 hour] Fleas, Ticks [(including those that may transmit Lyme Disease)], and kills mosquitoes and (chewing) lice.]

[Parastar<sup>®</sup> Plus For Dogs contains Fipronil and Cyphenothrin to effectively [start killing [ticks and] [fleas] in [just] [as little as] [5] [15] minutes [and for up to 30 days.] [Kills ticks, including those that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, anaplasmosis, and heptaozoonosis.] [kill fleas [(starts killing in [5][15] minutes)] [,] [and] ticks [(starts killing in [5][15] minutes)] [(including those that may transmit Lyme disease)], and kills [mosquitoes][and] chewing lice.]]\

[The active ingredients in Parastar<sup>®</sup> Plus [For Dogs] work by collecting in the hair follicles and skin oils. This product features a sustained-release formula developed for fast acting [and long lasting] control of fleas, ticks, mosquitoes and chewing lice for up to 30 days on dogs.]

### **READ ENTIRE LABEL BEFORE EACH USE.**

### **USE ONLY ON DOGS AND PUPPIES [OVER] 12 WEEKS OF AGE.**

[Parastar<sup>®</sup> Plus [For Dogs] kills fleas [in as little as 1 hour], ticks [in as little as 1 hour], mosquitoes and chewing lice. [Controls mites that may cause sarcoptic mange.] [Aids in control of mites that cause sarcoptic mange.] Kills deer ticks [that may transmit Lyme disease]. Kills brown dog ticks, American dog ticks, and lone star ticks. [Prevents flea reinfestation.]]

### **PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS. CAUTION.** Causes moderate eye irritation. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if absorbed through skin. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

**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. Overdosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, pregnant, nursing, debilitated or aged dogs.

### 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.



### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE.

**Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

FOR EXTERNAL USE ON DOGS ONLY. Do not allow your dog to ingest this product. Do not apply to puppies less than 12 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.] [weighing 45 [to] [–] 88 lbs.] [weighing 89[to] [–] 132 lbs.]. Do not split tubes 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.]

**How to open:** Remove product tube[s] [vial[s]] from the package. [Separate one tube from the others.] Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

**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<sup>®</sup> Plus [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[s] may be made if necessary, but do not apply more often than once every[[4] [four] weeks] [30 days] [month].

**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.

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-RG  
EPA Est. No. XXXXX-XX-XXX

**[BACK/SIDE CARTON LABEL - MASTER LABEL ENDS]**

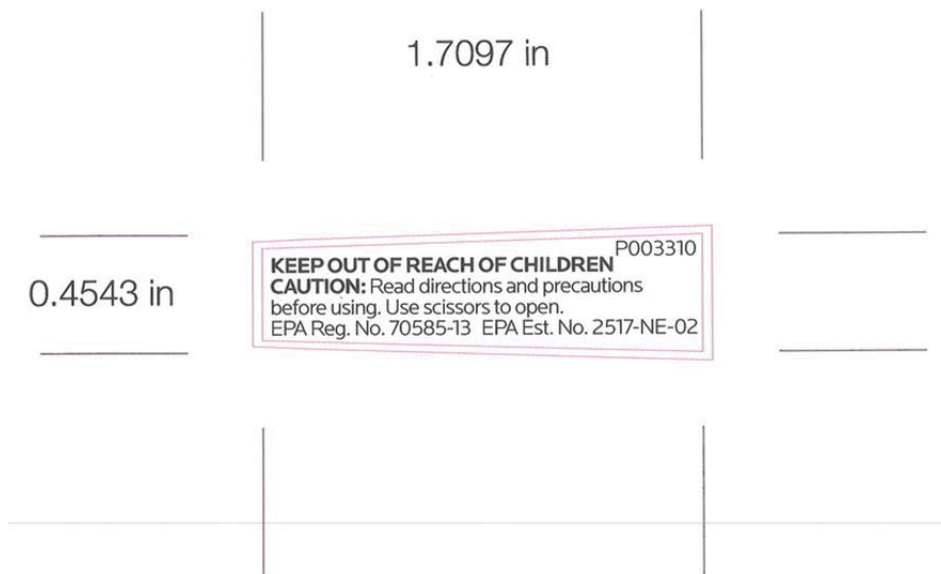
*BEGIN TUBE LABEL*

*FRONT OF TUBE:*



OR [For use only on dogs & puppies 12 weeks or older & weighing [4-22 lbs][23-44 lbs][45-88 lbs] [89-132 lbs]]  
OR [[.023] [.045] [.091] [.136] fl. oz.] [[.67] [1.34] [2.68] [4.02] mL]

*BACK OF TUBE:*



*END TUBE LABEL*

## **[OPTIONAL INSERT – START]**

[IF INSERT IS NOT PROVIDED, DETAILS WILL BE ON THE CARTON, WITH A FLAP]

### **KEEP OUT OF REACH OF CHILDREN CAUTION**

#### **PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS. CAUTION** Causes moderate eye irritation. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if absorbed through skin. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

**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 spot on topically applied pesticide at a time. Overdosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, pregnant, nursing, debilitated or aged dogs.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.  
**READ ENTIRE LABEL BEFORE EACH USE.**

**Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. Do not allow your dog to ingest this product. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately. FOR EXTERNAL USE ON DOGS ONLY. Do not apply to puppies less than 12 weeks of age. Do not apply to dogs weighing less than 4 lbs. For use only on dogs[ [&] [and] puppies] [weighing 4 [to][-] 22 lbs.] [weighing 23 [to] [-] 44 lbs.] [weighing 45 [to] [-] 88 lbs.] [[&] [and] weighing 89 [to] [-] 132 lbs.][Do not split tubes between dogs.] [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.] **Best if used year round.** DO NOT USE ON CATS or animals other than dogs. Separate the treated dog from cats for 24 hours after application. Cats and dogs that actively groom or engage in close physical contact with treated dog may be at risk of serious harmful effects. Cats exhibiting symptoms from ingestion (excessive salivation and foaming at the mouth) should be taken to the veterinarian immediately. If your dog is exhibiting signs of and/or are being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

**How to open:** Remove product tube[s] [vial] from the package. [Separate one tube from the others.] Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

**How to apply:** Invert the [tube] [vial] and use the open end to part the dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every [[4] [four] weeks] [30 days] [month].

### **FREQUENCY OF APPLICATION**

Use Parastar<sup>®</sup> Plus [For Dogs] monthly for complete control of flea, tick [and] chewing lice [and mosquito] [infestations]. [[Studies show that] Parastar<sup>®</sup> Plus [For Dogs] kills adult fleas [starts killing in as little as 1 hour)] [[starts killing] [starts to kill] in [5][15] minutes] [for up to three months]. If your dog is at high risk of flea reinfestation [, or in a highly infested environment], apply monthly. Apply monthly to control ticks[, mosquitoes] and chewing lice. [Parastar<sup>®</sup> Plus [For Dogs] kills mosquitoes within 24 hours for up to the first 7 days after application, then within 48 hours for up to 28 days.] Parastar<sup>®</sup> Plus [For Dogs] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

**For use only on Dogs Weighing [Between 4 [-] [and] 22 lbs.] [4 [to] [-] 22 lbs.]**

**{For cartons containing .67ml (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.)]] [as a spot on the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

**For use only on Dogs Weighing [Between 23 [-] [and] 44 lbs. ] [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.)]] [as a spot on the dog's back between the shoulder blades.] [from the back of the neck to a point midway between the neck and tail].

**For use only on Dogs Weighing [Between 45 [-] [and] 88lbs.] [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.)]] [as a spot on the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

**For use only on Dogs Weighing [Between 89 [-] [and] 132 lbs.] [89[to] [-]132 lbs.]**

**{For cartons containing 4.02ml (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.]

<b>FIRST AID</b>	
<b>If In Eyes</b>	<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 further treatment advice.</li> </ul>
<b>If On Skin Or Clothing</b>	<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>If Swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or 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>
<b>HOT LINE NUMBER</b>	
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.	
<b>NOTE TO PHYSICIAN OR VETERINARIAN</b>	
Treat patient symptomatically	

## **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: Novartis Animal Health US, Inc., (address).]

For Technical Information, call 1-800-637-0281 [For more information] [Hours of service] Non-Emergency call (number) [Made in USA]

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

EPA Reg. No. 70585-RG  
EPA Est. No. XXXXX-XX-XXX

**[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**

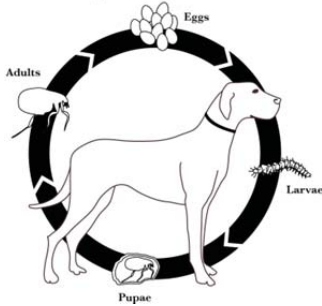
1. Remove product [tube[s]] [vial] from the package.
2. [Separate one tube from the others.] Holding the [tube] [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

**How to apply:**

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube 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]**

### Flea Life Cycle



[Look at the Label (Look at the Label icon) 6 Step [Easy] [Parastar<sup>®</sup> Plus [For Dogs] ] [Spot On] [Squeeze-On] Checklist

- Read the label completely and follow directions
- Weigh your dog
- Do NOT use Dog products on Cats
- Do NOT treat with more than one pesticide product at a time
- Separate animals after application to avoid chance of ingestion
- Do NOT split tubes between dogs [and use the ENTIRE tube contents]

### Parastar<sup>®</sup> Plus [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<sup>®</sup> Plus [For Dogs] every 30 days.]

[Apply Parastar<sup>®</sup> Plus [For Dogs] monthly for continuous protection against Fleas, Ticks, [and] chewing lice [and mosquitoes].]

[For year round protection apply Parastar<sup>®</sup> Plus [For Dogs] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[[First] [1<sup>st</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Second] [2<sup>nd</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Third] [3<sup>rd</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Fourth] [4<sup>th</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Fifth] [5<sup>th</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Sixth] [6<sup>th</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Seventh] [7<sup>th</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Eighth] [8<sup>th</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Ninth] [9<sup>th</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Tenth] [10<sup>th</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Eleventh] [11<sup>th</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[[Twelfth] [12<sup>th</sup>]] [dose] [Application] (Empty blank for owner to fill in date)]

[calendar stickers with brand name] [Place stickers on your calendar as a reminder to reapply [brand name] [in 30 days.]

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

[calendar stickers with Parastar<sup>®</sup> Plus [For Dogs]]

[[1] [2] [3] [4] [5] [6] [12] [24]-month] [application tracker]

[Enclosed for your convenience are [one][1] [two] [2] [three] [3] [four] [4] [five] [5] [six] [6] [seven] [7] [eight] [8] [nine] [9] [ten] [10] [eleven] [11] [twelve] [12] stickers.] [Place stickers on your calendar every 30 day from initial treatment as a reminder to reapply Parastar® Plus [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® Plus [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.]

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



**[INSERT – END]**

EPA (*approval date*)