



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 13, 2023

Jennifer Schofield
Advisor, Reg. Innovation
Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140

Subject: Label Amendment –Addition of stewardship commitment statements and label mitigation
Product Name: PNR1427 Insecticide (Brand name Seresto Large Dog and Seresto Small Dog)
EPA Registration Number: 11556-155
Application Date: June 9, 2023
Decision Number: 592348

Dear Jennifer Schofield:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable under FIFRA Section 3(c)(5) subject to the following conditions:

1. You must submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the U.S. Environmental Protection Agency (EPA or the Agency) requires all registrants of similar products to submit such data.
2. This registration is time-limited and expires five years from the date of this letter. Elanco US Inc. may request extension of the time-limited registration, or removal of the expiration date. An amendment request for these changes must be submitted at least one year prior to the expiration date and is subject to EPA Review.
3. Elanco US Inc. must submit annual enhanced incident reports and annual sales information in doses sold for this product in the EPA developed templates found at <https://www.epa.gov/pesticides/use-standardized-templates-report-pet-spot-incidents-conclusion-pilot-and-implementation>. The data are to be provided no later than the end of the first quarter of the following year (e.g., 2023 data no later than 31 Mar 2024). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and annual sales information to the Product Manager's attention in addition to your regular reporting of incidents through electronic submission.
4. Elanco US Inc. must submit an annual report, similar to a modified Food and Drug Administration (FDA) Annual Periodic Drug Experience Report, which provides an update on stewardship efforts and analysis of safety information collected the preceding

year. This additional analysis must be submitted together with Elanco US Inc.'s annual submission of detailed case data (Item #3) and will include:

- a. Update on execution of stewardship efforts.
 - b. Brief summary of the incidence rates of reports of adverse effects during the preceding year.
 - c. Detailed analysis of any serious adverse effects that have increased in frequency during the preceding year.
 - d. Overall evaluation of the benefit-risk profile of the product, taking into account adverse effect data and any other new or emerging safety information.
5. Elanco US Inc. must develop and implement additional efforts regarding case follow-up, referrals, and necropsies as medically indicated. Annually, Elanco US Inc. must review and update training materials, frequency of training, and technical solutions for collecting and providing data related to the pets involved in adverse event (AE) reports for all Elanco US Inc. staff responsible for taking in these data. Elanco US Inc. will, to the fullest extent possible, include the following information for each AE:
- a. Pre-existing medical conditions (e.g., hypothyroidism, diabetes), including previous history of reported condition.
 - b. Medications concomitantly administered.
 - c. Pet's prior experience with the product.
 - d. Pet health status

Elanco US Inc. must report on these efforts one year from the registration and has committed to continuing these efforts moving forward.

6. Elanco US Inc. must develop and implement a communications initiative to ensure the US veterinary community is informed of risks and benefits associated with use of pesticides in pet products, including Seresto, and the importance of reporting AEs. Those communications will include, at a minimum:
- a. A discussion of pesticide products in pet health – risks and AE reporting (including phone numbers relevant to reporting for Elanco US Inc. products).
 - b. A reminder that a Post Approval Experience (PAE) section is now on the label, including reported adverse events as listed below, and the owner is recommended to remove the collar and consult their veterinarian if these symptoms occur.
 - i. AEs in dogs are listed in decreasing order of reporting frequency: pruritus (itchy skin), vomiting, lethargy, behavioral disorders, application site reactions (dermatitis, inflammation, eczema, alopecia or lesions), anorexia, hyperactivity, muscle tremor, vocalization, convulsion, ataxia (problems with balance and coordination).
 - c. An update on outcomes of EPA's Seresto review
 - d. Elanco US Inc. will utilize the following items for delivery:
 - i. Submission of an educational article to a veterinary trade publication (e.g., DVM360, Vet Practice News)
 - ii. Submission of information to the Veterinary Information Network (VIN)
 - iii. Letter to pet health Doctors of Veterinary Medicine (DVMs)
 - iv. Email "blast" to drive DVMs to a webpage

- v. Elanco US Inc. web content with Frequently Asked Questions (FAQs) for DVMs
- vi. White paper which can be accessed online or sent out upon request by our pharmacovigilance (PV) call center

Elanco US Inc. must report on these efforts one year from the registration and provide a commitment to continuing these efforts moving forward. EPA may make recommendations to improve the outreach efforts after the 1-year review.

7. Elanco US Inc. must evaluate and summarize known characteristics of the release mechanism of the collar including testing performed to assess performance.
 - a. Elanco US Inc. must assess potential modifications of the release mechanism to optimize performance without compromise to collar retention under normal conditions of use.
 - b. Elanco US Inc. must report on these efforts one year from the registration and provide a commitment to continuing these efforts moving forward.
8. If, after formal consultation with the appropriate Service(s), additional modifications are identified in the Service's Biological Opinion(s) for imidacloprid, EPA will notify Elanco US Inc. in writing consistent with the terms in the Biological Opinion of any necessary required changes. Elanco US Inc. must submit an application for amendment incorporating any required changes, including amended labels, consistent with the timeline specified in EPA's notification. Alternatively, Elanco US Inc. may respond by submitting a request for voluntary cancellation of this product. If Elanco US Inc. fails to comply with this term, Elanco US Inc. has agreed in prior written acceptance of these terms that EPA may cancel the registration under an expedited process under FIFRA 6(e).

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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 FIFRA 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.

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Your release for shipment of the product constitutes acceptance of these terms. If you fail to satisfy these terms, EPA will consider appropriate regulatory action including, among other things, cancellation in accordance with FIFRA Section 6, including cancellation under FIFRA section 6(e). If you have any questions, please contact OPP RD Ombudsman at OPP_RD_Ombudsman@epa.gov.

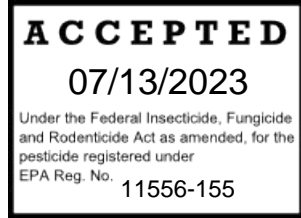
Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth Fertich". The signature is cursive and somewhat stylized.

Elizabeth Fertich
Product Manager 4
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs

Enclosure

NOTE TO REVIEWER: Braces “{ }” indicate notes to reviewer. Brackets “[]” indicate optional language.



PNR1427 Insecticide

Alternate Brand Names: Seresto Small Dog; Seresto Large Dog

{A large, clear picture of a dog in the appropriate weight range for the products will be on the outer container and/or insert.}

{Language for Small Collar}

For 8-month prevention and treatment of ticks, fleas, and lice on small dogs and puppies 7 weeks of age and older and up to [18 lbs.][8 kg][body weight]

{Language for Large Collar}

For 8-month prevention and treatment of ticks, fleas and lice for 8 months on large dogs and puppies 7 weeks of age and older and above [18 lbs.][8 kg] [[body weight]]

{Selected optional label claims bulleted, pictures and pictograms here from pages 7-12}

ACTIVE INGREDIENTS:	% by Weight
Flumethrin *	4.5%
Imidacloprid.	10.0%
OTHER INGREDIENTS	85.5%
TOTAL	100.0%

..

*Trans Z-1/trans Z-2 ratio: max 66% trans Z-1 and min 34% trans Z-2

Net Contents: [X] Collar [(s)] –XX oz. [XX grams] [per collar]	
EPA Reg. No. 11556-155	EPA Est. No. TBD

READ THE ENTIRE LABEL BEFORE USE

[USE ONLY ON DOGS]

DO NOT OPEN UNTIL READY TO USE

DO NOT LET CHILDREN PLAY WITH THIS COLLAR [OR REFLECTORS]

KEEP OUT OF REACH OF CHILDREN

[CHOKING HAZARD - CONTAINS SMALL PARTS]

See [[back][side]] [panel][insert]] for Directions for Use.

HOT LINE NUMBER
Have the product container or label with you when calling a poison control center or doctor or going for treatment.

- For CONSUMER QUESTIONS, call 1-800-255-6826.
- For medical emergencies involving HUMANS or ANIMALS, call 1-800-422-9874.
{or}
[For consumer questions and/or medical emergencies involving humans or animals call
1-800-255-6826]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

HOW TO APPLY

One collar per dog to be fastened around the neck.

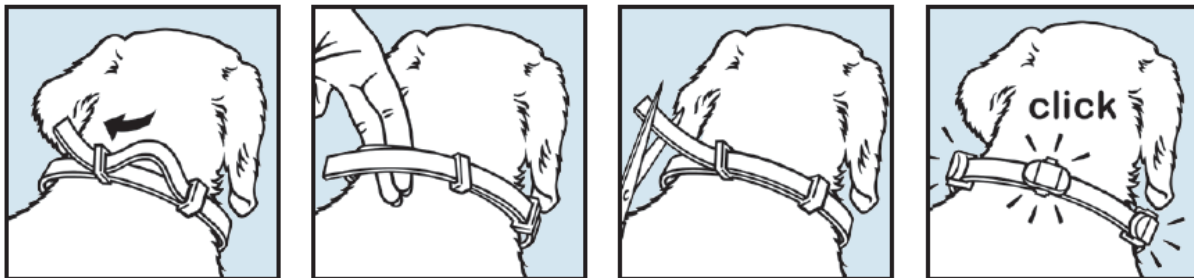
Remove collar from protective bag directly before use. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar.

{Optional marketing pictures here from pages 11-12}

Insert end of the collar through the buckle. Adjust the collar around the dog's neck without tightening it too tight or leaving it too loose. As a guide, fit 2 fingers comfortably between the collar and the neck. Pull excess collar through the loop(s). Cut collar to a length no greater than [1][one][an] inch (2 cm) beyond the loop(s) unless it is on a growing puppy where some additional length may be needed for adjustment as the animal grows.

[After application of the collar, three reflector clips may be fixed permanently to the collar to increase the animal's visibility in the dark. Take the clips out of the bag. The clips should be evenly distributed on the non-overlapping part of the collar. The clips are correctly applied when a clicking sound is heard. For safety reasons once the reflectors are fixed to the collar the reflector clasp closes permanently and cannot be re-opened.]

{Optional Visuals:4th picture in series depicting reflector snapping to collar is optional}



The collar should be worn continuously for the 8-month protection period. Check periodically and adjust fit if necessary, especially when puppies are rapidly growing.

This collar is designed with a release [system][mechanism]. In the unlikely event of a dog being trapped, the dog's own strength is usually sufficient to widen the collar to allow for quick release.

{Optional marketing pictures pages 11-12}

Replace the collar after 8 months for [[optimal][continuous]] flea and tick protection.

PRODUCT INFORMATION

Kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity (FBH).

[PNR 1427 Insecticide][ABN][This product][The collar] kills existing fleas on dogs 24 hours after initial application of the collar. After 24 hours, any new fleas on the dog are killed within 2 hours with protection against further flea infestation lasting eight (8) months. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions. Treat the dog's living areas with a product approved for home use [such as the Elanco line of home treatments].

Ticks already on the dog prior to treatment may not be killed immediately after collar application and may remain attached and visible. At the time of application remove ticks already on the dog. The prevention of infestations with new ticks starts at 48 hours after application of the collar.

Any new ticks on the dog are [repelled][killed][repelled and/or killed] as quickly as 6 hours after initial 48 hour application.

[[Kills lice [on dogs.]

[Seresto][PNR 1427 Insecticide][ABN][This product][The collar]] is water resistant and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight. Under normal conditions, effectiveness lasts for 8 months. In order to maintain an eight-month duration, dogs must not be bathed more than once per month. For dogs that swim once a month or more, the control duration is reduced to 5 months for flea control and reduced to 7 months for tick control.

In case of loss of collar, a new collar may be applied immediately. Do not attach a leash to the collar as this may cause breakage.

Keep the collar in the bag and in the outer packaging until use. As with any pesticide product, do not allow small children to play with the collar [or reflectors,] or to put them into their mouths. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and cold water after fitting the collar. People with sensitivity reactions to the ingredients of the collar should avoid contact with the collar. [Choking hazard. Contains small parts]. Do not place collar [or reflectors] in mouth. Not intended for use on humans.

Occasionally scratching may be observed in animals that are not used to wearing collars during the first few days after fitting. Ensure that the collar is not fitted too tightly. Slight hair loss and mild skin reactions from the collar may occur at the application site which usually recover within 1 or 2 weeks without the need for collar removal. For further guidance regarding individual animal sensitivities, see information below.

For external use on dogs only. Do not use on other animals. Do not use on puppies under [seven][7] weeks of age. Do not get this product in dog's eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, breeding, pregnant, or nursing animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets.

If your animal is on medication, consult your veterinarian before using this or any other product. The following adverse events are based on adverse event reporting. Not all adverse reactions are reported to EPA. It is not always possible to reliably estimate the adverse event frequency or establish a

causal relationship to product exposure using this data. The following adverse events in dogs are listed in decreasing order of reporting frequency: pruritus (itchy skin), eczema, lethargy, behavioral disorders, application site reactions (dermatitis, inflammation, eczema, alopecia or lesions), anorexia, hyperactivity, muscle tremor, vocalization, convulsion, ataxia (problems with balance and coordination). Remove the collar if these symptoms occur and consult with your veterinarian. Report suspected adverse events by calling Elanco [1-800-422-9874] {or} [1-800-255-6826] or the EPA website at <https://www.epa.gov/pesticide-incidents/report-pesticide-exposure-incidents-affecting-pets-or-domestic-animals>.

The [[patented][sustained][slow][steady][continuous][release][distribution]] technology ensures that both active ingredients are slowly and continuously released from the collar towards the animal. This ensures that concentrations of both active ingredients are present on the dog during the entire [[protection][efficacy]] period. The active ingredients spread from the site of direct contact over the skin surface.

{Optional Visual: depiction of release from matrix}

STORAGE AND DISPOSAL

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

Do not use container for food storage or other purposes.

Pesticide Storage: Store in original unopened container in a cool, dry place that is inaccessible to children.

Container Disposal: Dispose of pouch and expired collar in trash. Outer container may be recycled or disposed of in trash.

LIMITED WARRANTY, DISCLAIMER, AND LIMITATION OF DAMAGES

By using, buying or handling this product, user and/or buyer accepts the following terms. Subject to the adverse events referred to above, and to the extent consistent with applicable law, Elanco US Inc.'s ("Elanco") sole and exclusive limited warranty is that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label, when used in accordance with the label under normal use conditions. To the extent consistent with applicable law, the above exclusive express limited warranty is void if the product is used contrary to the label. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ELANCO MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ELANCO DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, AND DISCLAIMS ANY OTHER EXPRESS WARRANTY.** No agent of Elanco is authorized to make any other warranty, except in writing with a specific reference to this warranty. *To the extent consistent with applicable law, Elanco shall not be liable whatsoever for special, incidental or consequential damages resulting from the use or handling of this product. To the extent consistent with applicable law, the sole and exclusive remedy of the user and/or buyer for any and all losses, injuries, or damages, regardless of the legal theory, shall not exceed the purchase price paid for the product, or the replacement of product.* [The reflector clips contained herein are only meant to be used in combination with the specific collar and have been tested only for such use and purpose. To the extent consistent with applicable law, Elanco excludes liability for any misuse and use other than in combination with the specific collar as described in the packaging insert.] To the extent the above disclaimer of warranties disclaims implied warranties, it may be limited or ineffective if you are a "consumer" and this product is a "consumer product," as those terms are defined by the Magnuson Moss Act, 15 U.S.C. § 2301, in which case the duration of any implied

warranties is limited to the earlier of either the applicable statute of limitation or repose, and in no case will any implied warranty extend beyond the term of the Exclusive Express Limited Warranty for the product. To the extent consistent with applicable law, some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

EPA Reg. No. 11556-155

Manufactured For:
Elanco US Inc
2500 Innovation Way
Greenfield, IN 46140

Product of [Germany][USA]

Lot [No.]:

Pouch Label

[PNR 1427 Insecticide][ABN]

{A picture/image of a dog in the appropriate weight range for the products will be on the pouch.}

4.5% flumethrin

10.0% imidacloprid

Do not let children play with this collar [or reflectors].

FOR USE ON DOGS

See [outer container][leaflet][insert] for complete label information.

Do not open until ready to use.

{Selected optional label claims bulleted, pictures and pictograms here from pages 7-12}

Elanco US Inc

2500 Innovation Way, Greenfield, IN 46140

EPA Reg. No. 11556-155

EPA Est. No. TBD

Lot [No.]:

[Calendar Reminder Sticker]

[PNR 1427 Insecticide][ABN]

Use[[this][attached][included]] calendar sticker to remind you when your dog is due for its next application.

{Selected optional marketing picture here from pages 11-12}

Replace collar after 8 months

NOTE TO REVIEWER: Braces “{ }” indicate notes to reviewer. Brackets “[]” indicate optional language.

{Optional/Alternative Marketing Claims}

General Claims

1. Two active ingredients provide dual action against ticks, fleas, and lice [on dogs]
2. For use on dogs and puppies 7 weeks of age and older
3. Tick, [and] flea [and lice][prevention][control][and]treatment for dogs 7 weeks of age or older
4. [PNR 1427 Insecticide][ABN][This product] is indicated for the prevention and treatment of ticks, fleas and lice on dogs and puppies [7 weeks of age and older]
5. [Effective][Long-lasting][protection] against ticks and fleas for 8 months
6. [Effective][Long-lasting][protection] against ticks, fleas and lice for 8 months
7. Kills [and repels] ticks, [and] kills fleas [for 8 months]
8. Reliable 8-month protection against ticks, and fleas on dogs [and puppies]
9. Reliable 8-month protection against ticks, fleas and lice on dogs [and puppies]
10. [3-way] protection against fleas, ticks and lice
11. 8-month protection [against ticks and fleas] {[against ticks and fleas] will be used in close proximity to “8-month protection”}
12. 8-month protection against ticks, fleas and lice
13. For [small] dogs up to [18 lbs.][8 kg][body weight]
14. For [large] dogs above [18 lbs.][8 kg][body weight]
15. For external use on dogs
16. For [small dogs and puppies][large dogs]
17. Fully effective 48 hours after initial application of collar
18. Protects against ticks and fleas for 8 months
19. [8-month] [[protector band][pet collar][collar]]
20. [Kills][Protects] against ticks and fleas for 8 months
21. [Make sure to] replace [the] collar after 8 months [for year-round tick and flea [control][prevention]]
22. No need to remove [the] collar while bathing your dog. In order to maintain an eight-month duration, dogs must not be bathed more than once per month
23. No need to remove collar when [your] dog goes swimming. For dogs that swim once a month or more, the control duration is reduced to 5 months for fleas and 7 months for ticks.
24. [Seresto][PNR 1427 Insecticide][ABN][This product][The collar] is water resistant and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight. Under normal conditions, effectiveness lasts for 8 months. In order to maintain an eight-month duration, dogs must not be bathed more than once per month. For dogs that swim once a month or more, the control duration is reduced to 5 months for fleas and 7 months for ticks.
25. Fragrance-free
26. Odorless
27. No [noticeable] odor
28. Non-greasy
29. Easy to use
30. [[Easy][convenient]] [[to use][to apply]]
31. [[Graphite][Gray][Red][Yellow]] collar [color]
32. [Adjustable][convenient][easy-to-apply] collar
33. [Light] reflectors for added visibility [in the evening and at night]
34. [Three][3][visibility] reflector clips [included][for added pet visibility]
35. [Snap-on] reflectors [included] for added [night-time][pet][visibility]

36. One collar per dog [to be fastened around the neck]
37. Contains one collar
38. Sustained release technology for long-lasting flea and tick control for 8 months
39. [Elanco's] [Seresto's] patented polymer matrix system ensures that both active ingredients are continuously released, protecting pets from nose to tail.
40. [Elanco's] [Seresto's] patented polymer matrix technology ensures that both active ingredients are slowly released, protecting pets from nose to tail.
41. [Elanco's] [Seresto's] patented polymer matrix technology ensures that both active ingredients are slowly and continuously released.
42. The collar's patented polymer matrix technology ensures that both active ingredients are slowly and continuously released.
43. Patented [Elanco] [Seresto] polymer matrix: Effective flea and tick control for 8 continuous months.
44. Patented [Elanco] [Seresto] polymer matrix: Dependable flea and tick control for 8 continuous months.
45. Patented [Elanco] [Seresto] polymer matrix: Long lasting flea and tick control for 8 continuous months.
46. Patented [Elanco] [Seresto] polymer matrix: Reliable flea and tick control for 8 continuous months.
47. Continuous release technology ensures that both active ingredients are slowly released over time.
48. Slow-release technology ensures that both active ingredients are continuously released over time.
49. Steady release technology ensures that both active ingredients are slowly and continuously released over time.
50. Sustained release technology ensures that both active ingredients are slowly and continuously distributed over time.
51. Extended-release technology ensures that both active ingredients are slowly and continuously distributed over time.
52. Continuous release technology: Effective flea and tick control for 8 [continuous] months
53. Slow-release technology: Dependable flea and tick control for 8 [continuous] months
54. Steady release technology: Long-lasting flea and tick control for 8 [continuous] months
55. Sustained release technology: Reliable flea and tick control for 8 [continuous] months
56. Extended-release technology: Long-lasting flea and tick control for 8 [continuous] months
57. Slow-Release Effect: Active ingredients stored inside the polymer matrix gradually release over 8 [continuous] months
58. Slow-Release Collar: Active ingredients stored inside the polymer matrix gradually release over 8 [continuous] months
59. Slow-Release Protection: Active ingredients stored inside the polymer matrix gradually release over 8 [continuous] months
60. Extended Release: Active ingredients stored inside the polymer matrix gradually release over 8 [continuous] months
61. Extended-Release Collar: Active ingredients stored inside the polymer matrix gradually release over 8 [continuous] months
62. Continuous release of active ingredients over 8 [continuous] months
63. Extended release of active ingredients over 8 [continuous] months
64. Steady release of active ingredients over 8 [continuous] months
65. Steady distribution of active ingredients over 8 [continuous] months
66. [Long lasting][Continuous] flea and tick protection over 8 [continuous] months
67. 8 months of continuous flea and tick protection
68. Contains [Elanco's] [Seresto's] patented polymer matrix [system][technology].
69. Contains [Elanco's] [Seresto's] patented polymer matrix [collar][technology]

70. Extended-release technology
71. Continuous release technology
72. Steady release technology
73. Slow-release technology
74. No activation needed
75. Use[[this][attached][included]] calendar sticker to remind you when your dog is due for its next application.
76. [Sustained][Slow] release technology for effective flea and tick control for 8 months.
77. [Extended][Continuous] release technology for reliable flea and tick control for 8 months.
78. [Extended][Continuous] release technology for long lasting flea and tick control for 8 months.
79. Steady release technology for dependable flea and tick control for 8 months.

Tick Claims

80. Repels and kills ticks for 8 months , including [[Deer][Black-legged]] ticks, [*Ixodes scapularis*][that may transmit Lyme disease and anaplasmosis], American dog ticks, [*Dermacentor variabilis*][that may transmit Rocky Mountain spotted fever and ehrlichiosis], Brown dog ticks, [*Rhipicephalus sanguineus*][that may transmit ehrlichiosis, anaplasmosis, bartonellosis, babesiosis, canine hemoplasmosis, and Rocky Mountain spotted fever], and Lone Star ticks [*Amblyomma americanum*][that may transmit ehrlichiosis]
81. Treatment with [PNR 1427 Insecticide][ABN][this product][the collar] kills ticks that may transmit Anaplasmosis [*Anaplasma phagocytophilum*], Bartonellosis [*Bartonella vinsonii*, *Bartonella* spp.], Babesiosis [*Babesia canis*, *B. gibsoni*], Borreliosis [*Borrelia burgdorferi*], canine hemoplasmosis [*Mycoplasma haemocanis*], Ehrlichiosis [*Ehrlichia canis*, *E. chaffeensis*, *E. ewingii*], Hepatozoonosis [*Hepatozoon canis* and *H. americanum*], and Rickettsiosis [*Rickettsia rickettsii*][,which are types of [canine] vector borne diseases]
82. Efficacy against ticks [by repelling and killing]that may transmit Anaplasmosis [*Anaplasma phagocytophilum*], Bartonellosis [*Bartonella vinsonii*, *Bartonella* spp.], Babesiosis [*Babesia canis*, *B. gibsoni*], Borreliosis [*Borrelia burgdorferi*], canine hemoplasmosis [*Mycoplasma haemocanis*], Ehrlichiosis [*Ehrlichia canis*, *E. chaffeensis*, and *E. ewingii*], Hepatozoonosis [*Hepatozoon canis* and *H. americanum*], and Rickettsiosis [*Rickettsia rickettsii*][,which are types of [canine] vector borne diseases]
83. Kills [[Deer][Black-legged]] ticks[, that may transmit Lyme disease and Anaplasmosis]
84. Kills American dog ticks[,that may transmit Rocky Mountain spotted fever and Ehrlichiosis]
85. Kills all [[life][blood feeding]] stages of ticks
86. Kills tick adults, larvae, and nymphs
87. Kills existing ticks at48 hours of [initial] application
88. Prevents new tick infestations 48 hours after [initial] application
89. 48 hours after [initial] application, any new ticks are [repelled][killed][repelled and/or killed] in as quickly as 6 hours
90. Protects against ticks [on your dog]
91. Protects your [dog][and/or][puppy] from ticks [for 8 months]
92. Easy, effective [treatment and prevention][control] of ticks, [and] fleas[, and lice]

Flea Claims

93. [[Rapidly][Quickly]] Kills fleas on dogs 24 hours after [initial] application and continues to prevent infestations for 8 months
94. Kills and repels fleas before they lay eggs
95. Kills adult fleas and flea larvae
96. Kills flea larvae
97. After 24 hours of [initial] application, any new fleas are killed within 2 hours with protection against further flea infestation lasting 8 months

98. Protects your [dog][and/or][puppy] from fleas [for 8 months]
99. For the treatment and prevention of flea infestations on your dog
100. One treatment prevents further flea infestations on dogs for 8 months
101. Controls existing flea infestations by killing adult fleas
102. Prevents reinfestations by killing adult fleas before they lay eggs
103. Treatment with [PNR 1427 Insecticide][ABN][this product][the collar] kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity (FBH)
104. For prevention and treatment of flea infestation(s) for 8 months
105. [8-month] prevention and treatment of cat fleas [*Ctenocephalides felis*] and dog fleas [*Ctenocephalides canis*] on dogs
106. Kills cat fleas [*Ctenocephalides felis*] and dog fleas [*Ctenocephalides canis*] on dogs
107. Treatment with [PNR 1427 Insecticide][ABN][this product][the collar] kills fleas that may transmit tapeworm infections [*Dipylidium caninum*], Bartonellosis [*Bartonella vinsonii*, *Bartonella* spp.], and Rickettsiosis [*Rickettsia felis*][,which are types of [canine] vector borne diseases]
108. Efficacy against fleas that may transmit tapeworm infections [*Dipylidium caninum*], Bartonellosis [*Bartonella vinsonii*, *Bartonella* spp.], and Rickettsiosis [*Rickettsia felis*] [,which are types of [canine] vector borne diseases]
109. Kills fleas that may cause flea bite anemia [in dogs]
110. Kills fleas which may be a source of flea allergy dermatitis (FAD) [in dogs]

Flea & Tick Claims

111. REPELS AND kills fleas and ticks and kills lice on dogs and puppies 7 weeks of age and older and above 18 lbs. (8kg)
112. REPELS AND kills fleas and ticks and kills lice on dogs and puppies 7 weeks of age and older and up to 18 lbs. (8kg)
113. REPELS AND kills fleas and ticks and kills lice [on dogs]
114. REPELS AND kills fleas and ticks [on dogs]

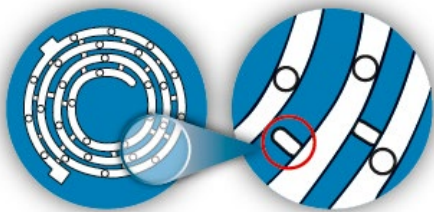
Lice & Other Efficacy Claims

115. Kills [[biting][chewing]] lice
116. For treatment and prevention of [[biting][chewing]] lice [infestations]
117. Controls existing [[biting][chewing]] lice infestations
118. Treats, prevents and controls [[biting][chewing]] lice [infestations]
119. Provides effective control of [[biting][chewing]] lice [infestations]
120. Kills [[biting][chewing]] lice and prevents further infestations
121. For treatment and prevention of infestations of [[biting][chewing]] lice

{Optional marketing pictures and pictograms}



{Representative dog; each carton may have a representative picture of a dog in that weight range}





Fleas



Ticks



Flea Larvae



Lice



Mobius Loop on outer container



Package

