

#### OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

March 11, 2025

Prince M. Bamaze Regulatory Affairs Sergeant's Pet Care Products, LLC 10077 South 134th Street Omaha, NE 68138-3710

Subject: Label Amendment - Registration Review Mitigation for Etofenprox and

Pyriproxyfen

Product Name: ETOFENPROX/NYLAR SPOT-ON FLEA AND TICK FOR DOGS &

**PUPPIES** 

EPA Registration Number: 2517-133

Application Dates: 04/30/2024 and 3/11/2025

Decision Number: 595727, 596842

#### Dear Prince M. Bamaze:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Etofenprox and Pyriproxyfen Interim Decisions, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

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 Assurance.

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A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling and must be used at your next label printing. You must submit one 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.

If you have any questions about this letter, please contact DeMariah Cotton by phone at (202)-566-2288 or via email at <a href="mailto:cotton.demariah@epa.gov">cotton.demariah@epa.gov</a>.

Sincerely,

Linda Arrington, Branch Chief Risk Management and Implementation Branch 4 Pesticide Re-Evaluation Division Office of Pesticide Programs

**ENCLOSURE:** Stamped label

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FRONT PANEL

**DOG SOUEEZE - ON** 

Pyriproxyfen (NYLAR), Etofenprox

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels.] {Information is instructional}

#### ETOFENPROX/NYLAR SPOT-ON FLEA AND TICK FOR DOGS & PUPPIES

{Market Label - the word 'Dog' will be 40-75% in height of the largest letter in the primary brand name.} {Market Label-a large clear picture of a Dog in the appropriate weight range will be on the front panel of the label} {See end of document for Alternate Brand Names (ABN) and Marketing Claims}

{A minimum of 1.5 cm x 1.5 cm icon as indicated black cat, black text, red circle and line through cat, on white background to ensure easy spotting, in lower right-hand corner of front label panel.}



{One of the statements below will appear prominently on the front panel of market label as required}

For use ONLY on dogs [&][and] puppies [weighing] [4-10 lbs.][11-20 lbs.], 12 weeks [of age] or older. {OR}

ONLY For dogs & puppies over 12 Weeks [of age], [4 to 10 lbs.] [11 to 20 lbs.]

{Text within box designates Vet Only language. All required text on Master Label applies to all type of packaging. The 'Vet Only language' applies additionally to labeling for products sold to Vets.}

**(SUBLABEL:** FOR USE ONLY BY LICENSED VETERINARIANS ON DOGS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION)

## FOR USE ONLY BY LICENSED VETERINARIANS ON DOGS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels.

Not for residential use. Do not repackage.

[Ideal for shelter use when under direct supervision of veterinarian]

[Professional Roll Pack]

[Convenient roll pack for in clinic use]

[Convenient roll pack for animal facility use]

[For use only by licensed veterinarians]

#### **ACTIVE INGREDIENTS:**

[Nylar® is a registered trademark of McLaughlin Gormley King Company]

### ACCEPTED

Mar 11, 2025

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

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# KEEP OUT OF REACH OF CHILDREN CAUTION

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

#### **Net Contents:**

[1][2][3][4][5][6][12] 0.068 fl oz (2.0 mL) [tube][vial] [s] [1][2][3][4][5][6][12] 0.135 fl oz (4.0 mL) [tube][vial] [s]

{[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][9][Nine][10][Ten][12][Twelve]}

**OR** {box only designates Vet Only language}

#### **Net Contents:**

[35][50][75][100][160] 0.068 fl oz (2.0 mL) [tube][vial] [s] [35][50][75][100][160] 0.135 fl oz (4.0 mL) [tube][vial] [s]

{[35][Thirty-five][50][Fifty][75][Seventy-five][100][One hundred][160][One hundred sixty]}

0.068 fl oz (2.0 mL) [tube] [vial] [s] *[for small dogs 4 to 10 lbs]* 0.135 fl oz (4.0 mL) [tube] [vial] [s] *[for small dogs 11 to 20 lbs]* 

{END - FRONT PANEL}

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BACK/SIDE PANEL

DOG SQUEEZE – ON Pyriproxyfen (NYLAR), Etofenprox

[Product Name]

# READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS [,] [AND] PUPPIES OVER 12 WEEKS OF AGE [AND] [WEIGHING] [4-10], [11-20] lbs

#### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS: CAUTION.** Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash 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 on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Overdosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product. This product is not a substitute for prescribed heartworm preventative.

**OR** {Text within box designates Vet Only language. All required text on Master Label applies to all type of packaging. The 'Vet Only language' applies additionally to labeling for products sold to Vets.}

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. This product is not a substitute for prescribed heartworm preventative. Do not treat a dog with more than one pesticide product at a time. Overdosing a dog can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction. If the dog is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

#### **FIRST AID**

**IF IN EYES**: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

PHYSICAL OR CHEMICAL HAZARDS: Combustible: Do not use or store near heat or open flame.

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#### **DIRECTIONS FOR USE**

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

For indoor use only. Use entire contents of [tube] [vial] on each dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Best if used year round. Households with more than one pet should not allow dogs or cats to groom each other until solution has dried. Application of product on pets must only be done indoors.

#### **RESTRICTIONS:**

Do not allow children to apply product.

Do not get this product in your dog's eyes or mouth.

Do not apply more often than once [a month] [every 30 days] [every 4 weeks].

Do not use on cats, rabbits or animals other than dogs.

Do not allow your dog to ingest this product.

Do not use on puppies under 12 weeks of age or less than [4] [11] lbs.

Do not bathe or allow dog to swim within 24 hours after application.

Do not apply more than one [tube][vial] per treatment for one dog regardless of dog's weight.

Do not reapply for [30 days][4 weeks][one month].

{Side Effects box to be located in the lower right hand corner of the back label panel immediately above the "cat prohibition" box}

**Side Effects**: Monitor your dog after application. [Some dogs may experience temporary startle effects when any 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 sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If any side effects occur or your dog has unusual reaction to the application, consult your veterinarian or call 1-800-781-4738. Consult your veterinarian before repeating application.

{A minimum of 1.5cm x 1.5cm cat prohibition icon and warning text will be in a box in the lower right hand corner of the back panel with black cat + red circle and line through the cat, black text, on white background to ensure easy spotting.}

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.



[See Insert inside [or] [Folded Panel(s)/Flap] for information on **How to open** and **How to apply**] {Referral Statement used only when 'Directions for Use' on outer packaging does not contain information below}

**How to open:** Remove product [tube(s)] [vial(s)] from the package. [Separate one [tube][vial] 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.] {**OR**} [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:** While holding the dog with one hand, use the other hand to apply the solution. Invert the [tube][vial] and use the narrow end to part the dog's hair while gently squeezing to apply to the dog's skin. 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 for use on Dogs weighing 4 to 10 lbs. and 12 weeks [of age] or older. Do not use on dogs less than 4 lbs. Apply contents of one (2.0 mL) [tube][vial] of [Product Name] [Squeeze-on] as a spot high on the back of the dog's neck behind its head and apply as a stripe to a point midway between the neck and the tail.]

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[Only for use on Dogs weighing 11 to 20 lbs. and 12 weeks [of age] or older. Do not use two [tubes][vials] on dogs greater than 20 lbs. Apply contents of one (4.0 mL) [tube][vial] of [Product Name] [Squeeze-on] as a spot high on the back of the dog's neck behind its head and apply as a stripe to a point midway between the neck and the tail.]

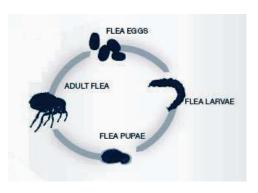
[Optional drawings that may or may not appear on finished label or insert]







[Insert diagram that includes checklist with magnifying glass and checklist graphic]



[Product name][Sergeant's][Sentry][Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] [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 [treatment][application] to avoid chance of ingestion
- Do NOT split [tube][vial][s] between dogs] [and use the ENTIRE [tube] [vial] contents]]

#### STORAGE AND DISPOSAL

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

**PESTICIDE DISPOSAL AND CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options.

#### **WARRANTY**

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. [[The directions for use of this product are believed to be adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer.]] Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

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In Case of Emergency, call: 1-800-781-4738 [Coupon(s) inside or on outside of box]

Non-Emergency, call: 1-800-224-PETS (7387) {When outside of the box, coupon will not cover or

distract consumer from required text}

[Made in USA for:] [Manufactured by:] [Distributed by:] [Lot code, date & Label code] [UPC CODE]

Sergeant's Pet Care Products, Inc. EPA Reg. No. 2517-133

Omaha, NE 68138-3710 EPA Est. No. XXX-XXX

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

#### TUBE/VIAL LABEL

#### DOG SQUEEZE-ON PYRIPROXYFEN (NYLAR), ETOFENPROX

{Front Label} {Back Label}

**{Brand Name} For Dogs** [4-10] [11-20] lbs

> 12 wks

Etofenprox 55.00%, Pyriproxyfen 2.20% 2.0 mL (or) 4.0 mL [Lot code] [label code]

KEEP OUT OF REACH OF CHILDREN CAUTION: Read entire label before each use. Use scissors to open. EPA Reg. No. 2517-133

{Lot No. is engraved on the crimp portion of the tube} {label code refers to an internal product tracking code} {EPA Reg. No. may be on either the front or back label}

{END - TUBE/VIAL LABEL}

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OPTIONAL INSERT OR FOLDED PANEL/FLAP

**DOG SQUEEZE - ON** 

Pyriproxyfen (NYLAR), Etofenprox

#### READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS [,] [AND] PUPPIES OVER 12 WEEKS OF AGE. [AND] [WEIGHING] [4-10], [11-20] lbs.

#### [Application Instructions] [Directions for Use]

[Product name][Sergeant's][Sentry][Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] [Checklist]

Read the label completely and follow directions

#### **RESTRICTIONS:**

•Do not allow children to apply product. •Do not get this product in your dog's eyes or mouth. • Do not apply more often than [once a month] [once every 30 days]. •Do not use on cats, rabbits or animals other than dogs. •Do not allow your dog to ingest this product. •Do not use on puppies under 12 weeks of age or less than [4] [11] lbs. •Do not bathe or allow dog to swim within 24 hours after application. •Do not apply more than one [tube][vial] per treatment for one dog regardless of dog's weight. •Do not reapply for [30 days][4 weeks][one month].

**How to open:** Remove product [tube(s)][vial(s)] from the package. [Separate one [tube][vial] 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.] {OR} [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:** While holding the dog with one hand, use the other hand to apply the solution. Invert the [tube][vial] and use the narrow end to part the dog's hair while gently squeezing to apply to the dog's skin. 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 for use on Dogs weighing 4 to 10 lbs. and 12 weeks [of age] or older. Do not use on dogs less than 4 lbs. Apply contents of one (2.0 mL) [tube][vial] of [Product Name] [Squeeze-on] as a spot high on the back of the dog's neck behind its head and apply as a stripe to a point midway between the neck and the tail.]

[Only for use Dogs weighing 11 to 20 lbs. and 12 weeks [of age] or older. Do not use two [tubes][vials] on dogs greater than 20 lbs.

Apply contents of one (4.0 mL) [tube][vial] of [Product Name] [Squeeze-on] as a spot high on the back of the dog's neck behind its head and apply as a stripe to a point midway between the neck and the tail.]

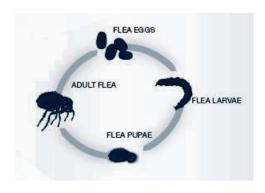
Optional drawings that may or may not appear on finished label or insert]







[Insert diagram that includes checklist with magnifying glass and checklist graphic]



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[ABNs:]

[Sergeant's Toy Breed Flea and Tick Squeeze-On for [Toy Breed] Dogs]

[Sergeant's Toy Breed Flea and Tick Squeeze-On for Small Breed Dogs]

[Sergeant's Toy Breed Flea and Tick Squeeze-On for Small and Toy Breed Dogs]

[Sergeant's Small Breed Flea and Tick Squeeze-On [for [Small [and Toy] Breed] Dogs]]

[SentryPro Toy and Small Breed Flea and Tick Squeeze-On [for [Small [and Toy] Breed] Dogs]]

[SentryPro Small Breed Flea and Tick Squeeze-On [for [Small [and Toy] Breed] Dogs]]

[Sentry®Pro XFT [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]

[Sentry®Pro XTR [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]

[Sentry®Pro XFC+ [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]

[SentryPro® XFTC [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]

[Sergeant's® Evolve TM [4] [11] Flea and Tick Squeeze-On for Dogs (and Puppies)]

#### [Optional marketing statements below may appear anywhere on the market label]

[with Nylar®] [Pyriproxyfen]

[[Toy] [and] [small] breed formula]

[Gentle protection for [toy] [small] breed dogs]

[For toy and small breeds [4-10 lbs][11-20 lbs]]

[For toy breeds 4-10 lbs.] [For small breeds 11-20 lbs]

[Formulated for Dogs and Puppies [[4-10][11-20], over 12 weeks old]]

[Formulated for [toy breed[s]] [and] [small breed[s]] dogs [[4-10][11-20], over 12 weeks old]]

[Apply once every [4 weeks] [1 month] [30 days]!]

[Up to [4 week] [1 Month] Dose!]

[(ICON Showing up to 4 Week Protection)]

[(One) (Two) (Three) (Four) (Six) Application(s)] [Bonus] 33% more [now includes 4 [tubes] [vials]]]

[Three Applications {for cartons with 3 tubes [vials]}] and/or [3 Month Supply] or [12 Week Supply]

[Four Applications {for cartons with 4 tubes [vials]}] and/or [4 Month Supply] or [16 Week Supply]

[Best if used year round!]

[Easy to Use Application]

[[Free] [Brochure] [and] [Calendar] [Stickers] Inside!]

[Patent pending technology]

[odorless] [unscented] [fragrance free]

[Dries quickly] [Quick drying formula] [Quick Drying]

[Squeeze-On] [stays on and doesn't rub off]

[Spreads by using the dog's natural skin oils]

[with Vitamin E] [No oily residue]

[Formulated] [with] DERMAshield<sup>TM</sup> [Technology]

[DERMAshield<sup>TM</sup> [Technology] [which] dries quickly to keep the product on the outer skin surfaces] [and contains [a vitamin] [vitamin E] to soothe skin]]

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#### (Multiple species)

[Flea and Tick control]

[Kills Fleas and Ticks] [for up to [30 days] [4 weeks] [one month]]

[Controls fleas, ticks, flea eggs & larvae]

[Flea, Tick and Flea Egg Treatment]

[Flea & Tick Control for Dogs & Puppies [4-10 [11-20], 12 weeks [old] and older]

[[Four] [4] Way Protection! Kills ticks, fleas, flea eggs & flea larvae]

[[Five] [5] [Way] [in one] Protection! Kills fleas, flea eggs, flea larvae, and ticks. Repels mosquitoes]

[Kills all stages of the flea life cycle]

[Kills fleas, ticks, flea eggs, and flea larvae]

[Flea, tick, flea egg and larvae control]

[Kills fleas, flea eggs, flea larvae, and ticks]

[Kills Fleas, Ticks, Flea Eggs & Flea Larvae for up to [4 Weeks] [1 month] [30 days]]

[Works for up to 4 Weeks on fleas and ticks!]

[Protects for up to 4 Weeks on [adult] fleas and ticks!]

[Up to 4 Week [One Month] [Adult] Flea and Tick [Control] [Protection!] [Treatment!]]

[Kills [Adult] Fleas and Ticks for up to 4 weeks!]

#### (Flea and Flea eggs and Larval)

[Kills [adult] fleas for up to [30 days] [4 weeks] [one month]]

[With [Nylar®] [Pyriproxyfen] to Break Flea Life Cycle]

[With Insect Growth Regulator to Break Flea Life Cycle]

[With [Nylar®] [Pyriproxyfen] Insect Growth Regulator which Breaks the Flea Life Cycle]

[Dual Action [!]: Etofenprox with [Nylar®] [Pyriproxyfen] IGR Effectively Breaks the Flea Life Cycle]

[Prevents Flea Eggs From Developing Into Biting Adults]

[Controls reinfestation for up to [70 days] [10 weeks]]

[[Breaks Flea Life Cycle!] for up to [70 Days] [10 Weeks]]

[Kills Flea Eggs and Larvae for up to [70 Days] [10 Weeks] [per application]]

[Kills fleas that may cause flea allergy dermatitis, and flea bite anemia] [for up to [30 days] [4 weeks] [one month]]

[Prevents flea eggs from developing into biting adults for up to [10 weeks] [70 days] [per application]]

[Kills for up to [10 weeks] [70 days] [flea eggs] [flea larvae]]

[Kills fleas]

#### (Ticks)

[Kills ticks [for up to [30 days] [4 weeks]]]

[Kills Ticks] [that may transmit Lyme Disease]

[Kills ticks including those that may transmit Lyme disease]

[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]

[Kills Deer Ticks (vector of Lyme Disease) for up to 4 weeks]

[Kills deer ticks [before they can] [that] [transmit Lyme Disease,] [for up to [4 weeks] [1 month] [30 days]]]

[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]

[Kills [brown dog ticks][(Rhipicephalus sanguineus)][for up to [4 weeks][1 month][30 days]]]

[Kills [American Dog Ticks][(Dermacentor variabilis)] for up to [4 weeks][1 month][30 days]!]

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#### (Mosquitoes)

[Repels mosquitoes]

[Repels mosquitoes] [for up to [28 days] [4 weeks] [1 month]!]

[Repels mosquitoes that may transmit heartworm]

[[Repels] [Prevents] mosquitoes that may transmit heartworm from feeding on dogs] [for up to [one month] [30 days] [4 weeks] [one month]]