

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 19, 2014

Intervet, Inc. d/b/a Merck Animal Health
c/o Mr. Micah T. Reynolds
Technology Sciences Group, Inc.
1150 18th Street, Suite 1000
Washington, DC 20036

Subject: PRIA Label Amendment – Addition of efficacy/marketing claims for effectiveness of product following use of antibacterial shampoo
Product Name: Activyl for Dogs and Puppies
EPA Registration Number: 773-94
Application Date: May 29, 2014
Decision Number: 491741

Dear Mr. Reynolds:

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable.

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 18 months from the date of this letter. After 18 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 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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please contact Julie Chao by phone at (703) 308-8735, or via email at chao.julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Meredith F. Laws". The signature is written in a cursive style with a large initial "M".

Meredith F. Laws, Chief
Insecticide-Rodenticide Branch
Registration Division
Office of Pesticide Programs

Enclosure

“Master Label for ACTIVYL® for Dogs and Puppies”:

This master label includes text for different size packages and application rates specific to pet’s age and body weight.

PRIMARY CARTON - FRONT PANEL STATEMENTS

ACTIVYL for Dogs and Puppies

Alternate Brand Names:

ACTIVYL for Dogs or Puppies
ACTIVYL Spot-On for Dogs and Puppies
ACTIVYL Spot-On for Dogs or Puppies
ACTIVYL for Dogs
ACTIVYL Spot-On for Dogs

Once-A-Month Topical Flea (Spot-On) (Treatment) (Prevention) (Control) for dogs and puppies 8 weeks and older and weighing

over (>) (greater than) 4 lb (pounds) (1.8 kg) and (up to) (less than or equal to) 14 lb (pounds) (6.6 kg) ONLY
over (>) (greater than) 14 lb (pounds) (6.6 g) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY
over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY
over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY
over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to)132 lb (pounds) (60 kg) ONLY

Active Ingredient:

Indoxacarb:

(S)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-trifluoromethoxy]phenyl]amino]-
-carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate.....19.53%

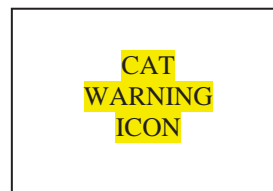
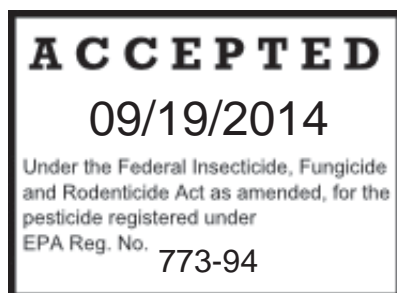
Other Ingredients:..... 80.47%

Total ..100.00%

KEEP OUT OF REACH OF CHILDREN WARNING

SEE BACK PANEL FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

GRAPHIC (note to reviewer: appropriate dog picture will be presented on the front panel depending on package)



() Bracket text allows for alternative presentations of the same claim.

PRIMARY CARTON - BACK PANEL STATEMENTS

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Refer to the package insert for complete Directions For Use.

RESTRICTIONS

▶ DO NOT ALLOW CHILDREN TO APPLY PRODUCT. ▶ TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. ▶ FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. ▶ USE ON DOGS ONLY. ▶ DO NOT USE ON DOGS (MALE OR FEMALE) INTENDED FOR BREEDING, OR ON DOGS THAT ARE PREGNANT OR NURSING. ▶ DO NOT USE ON OTHER ANIMALS. ▶ DO NOT APPLY MORE THAN ONCE PER MONTH. ▶ DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL IT IS COMPLETELY DRY. ▶ DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT.

FOR EXTERNAL USE ON DOGS AND PUPPIES ONLY.

For 0.51 mL package size: Do not use on dogs and puppies under 8 weeks of age and weighing less than 4 lb.
For 0.77 mL package size: Do not use on dogs and puppies under 8 weeks of age and weighing less than 14 lb.
For 1.54 mL package size: Do not use on dogs and puppies under 8 weeks of age and weighing less than 22 lb.
For 3.08 mL package size: Do not use on dogs and puppies under 8 weeks of age and weighing less than 44 lb.
For 4.62 mL package size: Do not use on dogs and puppies under 8 weeks of age and weighing less than 88 lb.

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, then continue rinsing eye. • Call a physician if irritation persists.

IF ON SKIN • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

IF SWALLOWED • Call poison control center or doctor immediately for treatment advice. • Have a person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling the poison control center or doctor or going for treatment. You may also contact the Rocky Mountain Poison Center at 1-303-595-4869 for emergency medical treatment information.

SIDE EFFECTS: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Individual sensitivities, while rare, may occur after using any pesticide product. Consult a veterinarian immediately.

PRIMARY CARTON - BACK PANEL STATEMENTS (cont'd)

For 0.51 ml/0.77 ml/1.54 ml/3.08 ml/4.62 ml

(Note To Reviewer: appropriate dose size will be depending on package)

1) Presentation for multi-pack outer carton – back panel:

<p>PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS WARNING. Causes substantial but temporary eye injury. Harmful if absorbed through skin or swallowed. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.</p> <p>HAZARDS CONTINUED ON SIDE PANELS</p>	<p>CAT WARNING ICON DO NOT USE DOG PRODUCT ON CATS – Keep cats away from treated dogs for 24 hours, or until product has dried. If applied to a cat or ingested by a cat, contact your veterinarian.</p> <p>Format – same size as marketing icons Yellow background with black text</p>
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2) Presentation for single pack outer carton – back panel:

<p>CAT WARNING ICON DO NOT USE DOG PRODUCT ON CATS – Keep cats away from treated dogs for 24 hours, or until product has dried. If applied to a cat or ingested by a cat, contact your veterinarian.</p> <p>Format – same size as marketing icons Yellow background with black text</p>	<p>PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS WARNING. Causes substantial but temporary eye injury. Harmful if absorbed through skin or swallowed. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.</p> <p>HAZARDS CONTINUED ON SIDE PANELS</p>
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() Bracket text allows for alternative presentations of the same claim.

PRIMARY CARTON - SIDE PANEL STATEMENTS

PRECAUTIONARY STATEMENTS (cont'd)

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs and puppies only. Do not use on puppies under 8 weeks of age and weighing less than 4 lb/14 lb/22 lb/44 lb/88 lb (note to reviewer: weight used will be according to package size). Do not use on dogs (male or female) intended for breeding, or on dogs that are pregnant or nursing. Consult a veterinarian before using this product on debilitated, aged, or medicated dogs. Individual sensitivities, while rare, may occur after using any pesticide product. If signs continue, consult a veterinarian immediately. Certain medications can interact with pesticides.

PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry place inaccessible to children and pets.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: If empty, do not reuse the container. Place in trash or offer for recycling if available. If partly filled, call your local solid waste agency for disposal instructions. Never place unused products down any indoor or outdoor drain.

Made in the USA

EPA Reg. No. 773-94

EPA Est. No. 618-LA-1

Net Contents: X applicator(s), each 0.02 fl.oz. (0.51 mL) {Total X fl.oz (X ml)}
 X applicator(s), each 0.03 fl.oz. (0.77 mL) {Total X fl.oz (X ml)}
 X applicator(s), each 0.05 fl.oz. (1.54 mL) {Total X fl.oz (X ml)}
 X applicator(s), each 0.10 fl.oz. (3.08 mL) {Total X fl.oz (X ml)}
 X applicator(s), each 0.16 fl.oz. (4.62 mL) {Total X fl.oz (X ml)}

Intervet Inc (d/b/a Merck Animal Health),
Summit, NJ 07901

LOGO Merck Animal Health

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Rev. xx/xxxx

(Volume varies with size of animal for which package is intended and number of applicators per package. Product may be packaged in 1, 3, 4, 6, or 12 applicators per package. Total volume will correspond to number of applicators)

() Bracket text allows for alternative presentations of the same claim.

APPLICATOR LABELING STATEMENTS

ACTIVYL

CAT WARNING ICON

Format – same size as marketing icons
Yellow background with black text

For Dogs (and) (or) Puppies 8 weeks and older and

over (>) (greater than) 4 lb (pounds) (1.8 kg) and (up to) (less than or equal to) 14 lb (pounds) (6.6 kg) ONLY
over (>) (greater than) 14 lb (pounds) (6.6 g) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY
over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY
over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY
over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to)132 lb (pounds) (60 kg) ONLY

Indoxacarb:19.53%

KEEP OUT OF REACH OF CHILDREN WARNING READ ENTIRE LABEL BEFORE USE

0.02 fl.oz. (0.51 mL) or
0.03 fl.oz. (0.77 mL) or
0.05 fl.oz. (1.54 mL) or
0.10 fl.oz. (3.08 mL) or
0.16 fl.oz. (4.62 mL) or

EPA Reg. No. 773-94
EPA Est. No. 618-LA-1

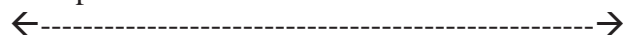
Intervet Inc (d/b/a Merck Animal Health). LOGO Merck Animal Health

Lot No:

() Bracket text allows for alternative presentations of the same claim.

FOIL POUCH LABELING STATEMENTS

To Open: Tear or cut across line with scissors



DO NOT REMOVE APPLICATOR (TUBE) UNTIL READY TO USE

ACTIVYL for Dogs and Puppies

CAT WARNING ICON

Format – same size as marketing icons
Yellow background with black text

Alternate Brand Names:

ACTIVYL for Dogs or Puppies
ACTIVYL Spot-On for Dogs and Puppies
ACTIVYL Spot-On for Dogs or Puppies
ACTIVYL for Dogs
ACTIVYL Spot-On for Dogs

For Dogs (and) (or) Puppies 8 weeks and older and

over (>) (greater than) 4 lb (pounds) (1.8 kg) and (up to) (less than or equal to) 14 lb (pounds) (6.6 kg) ONLY
over (>) (greater than) 14 lb (pounds) (6.6 g) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY
over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY
over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY
over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to)132 lb (pounds) (60 kg) ONLY

Indoxacarb: 19.53%

KEEP OUT OF REACH OF CHILDREN

WARNING

READ ENTIRE LABEL BEFORE USE

0.02 fl.oz. (0.51 mL) or
0.03 fl.oz. (0.77 mL) or
0.05 fl.oz. (1.54 mL) or
0.10 fl.oz. (3.08 mL) or
0.16 fl.oz. (4.62 mL) or

EPA Reg. No. 773-94
EPA Est. No. 618-LA-1

Intervet Inc (d/b/a Merck Animal Health). LOGO Merck Animal Health

Lot No:

() Bracket text allows for alternative presentations of the same claim.

(Due to carton size this additional information is referred to appear on the carton and includes complete directions for use with all carton box mandatory required statements found on the primary carton)

For 0.51 mL, 0.77 mL, 1.54 mL, 3.08 mL, 4.62 mL, package sizes
(Note To Reviewer: appropriate dose size will be depending on package)

PACKAGE INSERT STATEMENTS

CAT WARNING ICON
DO NOT USE DOG PRODUCT ON CATS -
Keep cats away from treated dogs
for 24 hours, or until product has
dried. If applied to a cat or
ingested by a cat, contact your
veterinarian.
Format – same size as marketing icons
Yellow background with black text

ACTIVYL for Dogs and Puppies

Alternate Brand Names:

ACTIVYL for Dogs or Puppies
ACTIVYL Spot-On for Dogs and Puppies
ACTIVYL Spot-On for Dogs or Puppies
ACTIVYL for Dogs
ACTIVYL Spot-On for Dogs

Once-A-Month Topical Flea (Spot-On) (Treatment) (Prevention) (Control) for dogs and puppies 8 weeks and older and weighing

over (>) (greater than) 4 lb (pounds) (1.8 kg) and (up to) (less than or equal to) 14 lb (pounds) (6.6 kg) ONLY
over (>) (greater than) 14 lb (pounds) (6.6 g) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY
over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY
over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY
over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to)132 lb (pounds) (60 kg) ONLY

Active Ingredient:

Indoxacarb:

(S)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-trifluoromethoxy]phenyl]amino]
-carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate.....19.53%

Other Ingredients:.....80.47%
Total ..100.00%

KEEP OUT OF REACH OF CHILDREN
WARNING

() Bracket text allows for alternative presentations of the same claim.

PACKAGE INSERT STATEMENTS (cont'd)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Refer to the package for complete Directions For Use.

RESTRICTIONS

▶ DO NOT ALLOW CHILDREN TO APPLY PRODUCT. ▶ TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. ▶ FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. ▶ USE ON DOGS ONLY. ▶ DO NOT USE ON DOGS (MALE OR FEMALE) INTENDED FOR BREEDING, OR ON DOGS THAT ARE PREGNANT OR NURSING. ▶ DO NOT USE ON OTHER ANIMALS. ▶ DO NOT APPLY MORE THAN ONCE PER MONTH. ▶ DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL IT IS COMPLETELY DRY. ▶ DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT.

FOR EXTERNAL USE ON DOGS AND PUPPIES ONLY.

For 0.51 mL package size: Do not use on dogs and puppies under 8 weeks of age and weighing less than 4 lb.
For 0.77 mL package size: Do not use on dogs and puppies under 8 weeks of age and weighing less than 14 lb.
For 1.54 mL package size: Do not use on dogs and puppies under 8 weeks of age and weighing less than 22 lb.
For 3.08 mL package size: Do not use on dogs and puppies under 8 weeks of age and weighing less than 44 lb.
For 4.62 mL package size: Do not use on dogs and puppies under 8 weeks of age and weighing less than 88 lb.

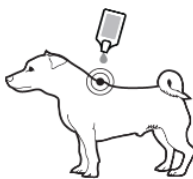
(HOW TO APPLY) Open one foil pouch and remove applicator (tube).



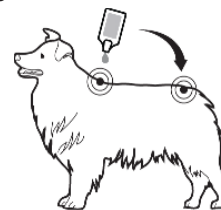
3. Graphics for specific dog sizes represented below – 1 graphic per package size



For dogs over 4 lb and up to 14 lb ONLY
(For dogs over 1.8 kg and less than 6.6 kg)
(0.51 mL size only)



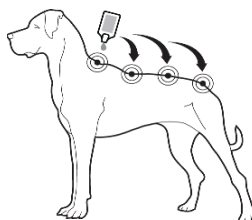
For dogs over 14 lb up to 22 lb ONLY
(For dogs over 6.6 kg up to 10 kg)
(0.77 mL size only)



For dogs over 22 lb up to 44 lb ONLY
(For dogs over 10 kg up to 20 kg)
(1.54 mL size only)



For dogs over 44 lb up to 88 lb ONLY
(For dogs over 20 kg up to 40 kg)
(3.08 mL size only)



For dogs over 88 lb up to 132 lb ONLY
(For dogs over 40 kg up to 60 kg)
(4.62 mL size only)

() Bracket text allows for alternative presentations of the same claim.

PACKAGE INSERT STATEMENTS (cont'd)

Step 1. Hold applicator (tube) in upright position away from your face and snap tip open by bending it and folding it back on itself.

Step 2. The dog should be standing for easy application. Part the hair and place applicator (tube) tip against the skin between shoulder blades.

Step 3. (*for small dog*): Squeeze applicator firmly applying entire contents directly to skin. Do not allow product to run off. Do not have contact with treated area (application site) until it is completely dry.

Step 4 (*Directions for larger dogs – medium, larger, and ex-large*):

Apply entire contents of tube evenly to a minimum of (two)(or)(three)(or)(four) spots on the back starting from between the shoulder blades and ending at the base of the tail. At each spot, part the hair until skin is visible. Place the tip of the applicator (tube) on the skin and gently squeeze a portion of the contents at each spot ensuring applicator is emptied at the last spot. Do not apply an excessive amount of solution at any one spot. Do not allow the product to run off. Do not have contact with the treated area(s) (application site(s)) until it is completely dry.

(*EDITORIAL – FOR DIRECTIONS FOR USE – DOGS OVER 88 LB UP TO 132 LB ONLY*)

DO NOT DOUBLE DOSE DOGS LARGER THAN 132 LB.

It is recommended to reapply every 30 days or as needed, but DO NOT apply more than 1 applicator (tube) per month. When application is complete, follow the Container Handling instructions under the Storage and Disposal section below.

FIRST AID	
If in Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a physician if irritation persists.
If On Skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have a person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling the poison control center or doctor or going for treatment. You may also contact the Rocky Mountain Poison Center at 1-303-595-4869 for emergency medical treatment information.	

SIDE EFFECTS: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Individual sensitivities, while rare, may occur after using any pesticide product. Consult a veterinarian immediately.

() Bracket text allows for alternative presentations of the same claim.

PACKAGE INSERT STATEMENTS (cont'd)

For 0.51 ml/0.77 ml/1.54 ml/3.08 ml/4.62 ml
(note to reviewer: appropriate dose size will be depending on package)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING. Causes substantial but temporary eye injury. Harmful if absorbed through skin or swallowed. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs and puppies only. Do not use on puppies under 8 weeks of age and weighing less than 4 lb/14 lb/22 lb/44 lb/88 lb (note to reviewer: weight used will be according to package size). Do not use on dogs (male or female) intended for breeding, pregnant or nursing. Consult a veterinarian before using this product on debilitated, aged, or medicated dogs. Individual sensitivities, while rare, may occur after using any pesticide product. If signs continue, consult a veterinarian immediately. Certain medications can interact with pesticides.

PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry place inaccessible to children and pets.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: If empty, do not reuse the container. Place in trash or offer for recycling if available. If partly filled, call your local solid waste agency for disposal instructions. Never place unused products down any indoor or outdoor drain.

EPA Reg. No. 773-94

EPA Est. No. 618-LA-1

Net Contents: X applicator(s), each 0.02 fl.oz. (0.51 mL) {Total X fl.oz (X mL)}
X applicator(s), each 0.03 fl.oz. (0.77 mL) {Total X fl.oz (X mL)}
X applicator(s), each 0.05 fl.oz. (1.54 mL) {Total X fl.oz (X mL)}
X applicator(s), each 0.10 fl.oz. (3.08 mL) {Total X fl.oz (X mL)}
X applicator(s), each 0.16 fl.oz. (4.62 mL) {Total X fl.oz (X mL)}

Made in the USA

Intervet Inc (d/b/a Merck Animal Health).
Summit, NJ 07901

LOGO Merck Animal Health

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Rev. xx/xxxx

(Volume varies with size of animal for which package is intended and number of applicators per package. Product may be packaged in 1, 3, 4, 6, or 12 applicators per package. Total volume will correspond to number of applicators)

() Bracket text allows for alternative presentations of the same claim.

FRONT PANEL AND/OR SIDE PANEL CLAIMS

1. Intended to be sold by veterinarians.
2. Intended to be dispensed (and)(or) sold through (by) licensed veterinarians and only to their clients for pets under a direct vet-client-patient relationship.
3. Product availability intended through licensed veterinarians.
4. Kills fleas that may cause disease, including bartonellosis and transmit tapeworms.
5. If there is a high risk of re-infestation or if the pet has fleas, once monthly application is recommended
6. Kills fleas that may cause (flea allergy dermatitis) (FAD).
7. If there is a high risk of re-infestation or if the pet has fleas which may cause (flea allergy dermatitis) (FAD), once monthly application is recommended.
8. (Alternate or brand name) kills fleas that may cause anemia.
9. (Alternate or brand name) kills fleas that may transmit tapeworms.
10. The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with (alternate or brand name) kills fleas
11. For the (prevention)(and)(treatment) of flea infestations on dogs (and/or) (puppies > 8 weeks) for (four)(4)(weeks) (one)(1)(month)
12. (Prevents) (and) (protects) against (re-)infestation (of fleas) for (four)(4)(weeks)
13. (Prevents) (and) (protects) against (re-)infestation (of fleas) for (one)(1)(month)
14. One treatment prevents flea infestations (on dogs) (and/or) (puppy > 8 weeks) for (four)(4)(weeks)
15. One treatment prevents flea infestations (on dogs) (and/or) (puppies > 8 weeks) for (one)(1)(month)
16. Protects (your dog) (and/or) (puppy > 8 weeks) from fleas for (four)(4)(weeks)
17. Protects (your dog) (and/or) (puppy > 8 weeks) from fleas for (one)(1)(month)
18. Monthly treatment (recommended) for optimal (control)(and)(prevention)(of fleas)(on your)(dog)(and/or)(puppy > 8 weeks)
19. Effective monthly (control) (prevention)(and)(treatment) of fleas (on dogs) (and/or) (puppies > 8 weeks)
20. Flea (control) (prevention)(and)(treatment) formulated for (dogs)(and)(puppies > 8 weeks)
21. (Controls)(Treatment against)(Protects against) (blood-feeding) (by) fleas
22. Monthly treatments are (recommended) for optimal (control) (and) (prevention) of flea(s) (infestations)
23. Prevents and controls re-infestations
24. For optimum treatment, control and prevention of adult year round treatment is recommended.
25. Prevents flea larval development
26. Larval flea stages in (the pet's) (your dog's) surroundings are killed following contact with (alternate or brand name) treated pet.

() Bracket text allows for alternative presentations of the same claim.

FRONT PANEL AND/OR SIDE PANEL CLAIMS (cont'd)

27. Water-resistant
28. Waterproof
29. (Alternate or brand name) (This product) Remains effective even after (bathing) (water immersion), (or) (exposure to rain) (or) (sunlight)
30. (Alternate or brand name)(This product) Remains effective after (bathing) (and) (or) (swimming)
31. (Alternate or brand name)(This product) remains efficacious following (a) (shampoo treatment) (swimming) (and) (or) (exposure to rain) (or) (sunlight).
32. Starts killing fleas within 8 hours
33. (Alternate or brand name) (This product) remains effective against cat fleas after antibacterial shampoo treatment

ALTERNATE MARKETING TEXT

1. Once-A-Month Topical Flea (Treatment) (Prevention) (Control) for (dogs) (and) (puppies > 8 weeks)
2. Once-A-Month Topical Flea (Treatment) (Prevention) (Control) for (dogs) (and) (puppies) > 8 weeks and older and weighing more than 4 lb.
3. (Once) monthly (a month) application (treatment) (for)(dogs) (and) (puppies > 8 weeks)
4. (Reapplication at monthly intervals) (Monthly reapplications) may be appropriate depending upon (the level of flea challenge) (and) (animal sensitivities) (i.e., flea allergy dermatitis).
5. X applicators
6. X monthly doses (applications)(treatments)
7. Quick drying (non-greasy)
8. Long Lasting (Fast Acting) for up to 1 month (30 days)
9. (Effective) Long-lasting protection for up to 1 month (30 days).
10. Easy to apply (spot-on) (topical) (application)(treatment)
11. Convenient (to use)(monthly use)(monthly treatment)
12. Easy (Convenient) to apply
13. Easy (spot on) (to use) application
14. (Convenient) (Single) (Spot) application
15. No (noticeable) odor.
16. Fragrance free
17. Formulated for dogs (and) (puppies) > 8 weeks and older and weighing more than 4 lb.
18. Monthly use breaks the flea life cycle
19. Questions (or) (comments) call (1-800-Tel. Number)(or)(Tel. No.)
20. For more information call (1-800- Tel. Number) (or Tel. No.)
21. For emergencies call (1-800- Tel. Number) (or) (Tel. No.)-same as above
22. If you have any questions, call Technical Services at (1-800- Tel. Number)(or) (Tel. No.)
23. (Manufacturer) (Satisfaction) Guaranteed or your money back.

ALTERNATE MARKETING TEXT (cont'd)

24. Recommended year round (control) (treatment)(prevention) (against fleas)
25. Proven (control)(treatment)(prevention) for flea infestations
26. Protects (your) (dog) (and) (or) (puppy > 8 weeks) for (1 month)(one month)(a month)
27. (Alternate or brand name)(This product)(It) may also be used to (control) (prevent) infestation on flea-free (dogs) (and) (or) (puppies) > 8 weeks (of age) or older and weighing more than 4 lb., taken into a flea-contaminated environment.
28. Flea control for today's flea challenges
29. Indoxacarb is from the chemical class of oxadiazine insecticides
30. Excellent flea mortality
31. Pesticidal
32. (Indoxacarb is a)Voltage-dependent sodium channel blocker
33. Indoxacarb (the active) (in brand name) (in this product) blocks the channels that regulate the flow of sodium through the insect's nervous system.
34. (Convenient) (Single) (Spot) application that provides (control)(treatment)(protection) (of)(from)existing (flea)(infestations)
35. Protects against reinfestation(s) (of) (fleas) (on) (your) (dog) (puppy > 8 weeks)
36. When used monthly (alternate or brand name) (this product) breaks the flea life cycle.
37. (Alternate or brand name) (This product) can be used on puppies > 8 weeks of age and weighing more than 4 lb.
38. Water-resistant
39. Waterproof
40. (Alternate or brand name)(This product) Remains effective even after (bathing) (water immersion), (or) (exposure to rain) (or) (sunlight)
41. (Alternate or brand name)(This product) Remains effective after (bathing) (and) (or) (swimming)
42. (Alternate or brand name)(This product) remains efficacious following (a) (shampoo treatment) (swimming) (and) (or) (exposure to rain) (or) (sunlight).
43. Product contained in child resistant packaging

NEXT DOSE STICKERS/ TREATMENT REMINDER (prototype)

Use these handy stickers to help remember when your pet’s next dose is due. When you use the last tube in this package, consult your veterinarian and order more (product) (alternate or brand name), if needed.

Attach these (stickers) (reminders) to your (wall) (desk) calendar (daily planner) on the days the first dose is to be given, and on the same date for each of the remaining months.

Alternate text

It may be hard to remember when your (dog’s) (and/or) (puppy’s > 8 weeks) next dose is due. The following has been developed as a tool to help you keep track of every dose. When you use the last tube in this package, consult your veterinarian and order more (product) (alternate or brand name), if needed.

Attach these (stickers) (reminders) to your (wall) (desk) calendar (daily planner) on the days the first dose is to be given. Place another (sticker) (reminder) on the same date for the remaining months.

STICKER PROTOTYPE:

Picture of dog may vary. Up to 12 sticker count consistent with package



CARD Prototype:

PET’S NAME
PRODUCT: (preprinted alternate brand name)
DATE OF 1 st APPLICATION:
DATE OF 2 nd APPLICATION:
DATE OF 3 rd APPLICATION

() Bracket text allows for alternative presentations of the same claim.