



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

EPA Reg. Number:

773-94

Date of Issuance:

3/30/18

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 06/05/2020

Name of Pesticide Product:

Activyl For Dogs and Puppies

Name and Address of Registrant (include ZIP Code):

Micah T. Reynolds
Ivernet, Inc. (d/.b/a Merck Animal Health
2 Giralda Farms
Madison, New Jersey 07840

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:

Richard Gebken, Product Manager 10
Invertebrate & Vertebrate Branch 2
Registration Division (7505P)
Office of Pesticide Programs

Date:

3/30/18

2. The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is extending the two-year registration restriction. This registration is time-limited and expires 06/05/2020.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in the letter dated 06/2/2016 and the initial Notice of Registration dated 6/29/2010.

You are required to comply with the data requirements described in the DCIs identified below:

a. Indoxacarb GDCI-067710-1382

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

4. 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.

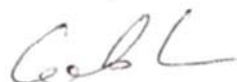
If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 09/19/2008

If you have any questions, please contact Richard Gebken by phone at (703) 305-6701, or via email at gebken.richard@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Invertebrate & Vertebrate Branch 2
Registration Division (7505P)
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

(Note: “for Dogs and Puppies” text in primary brand name, and other iterations in the alternate brand names that follow “Activyl” to be a minimum of 75% as large as the height of the largest letter in the brand name presentation.)

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 (TOY)
over (>) (greater than) 14 lb (pounds) (6.6 g) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY (S)
over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY (M)
over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY (L)
over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to)132 lb (pounds) (60 kg) ONLY (XL)

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%

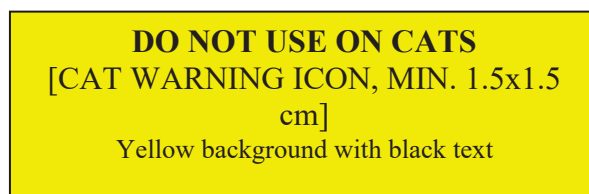
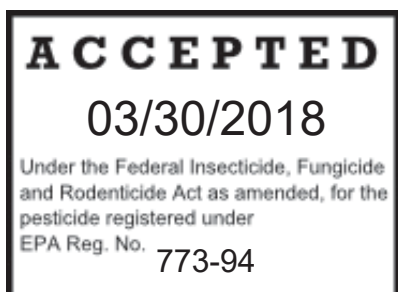
Other Ingredients:.....80.47%
Total ..100.00%

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 CATS OR 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. Do not apply to dogs weighing less than 4 lb.

For 0.77 mL package size: Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 14 lb.

For 1.54 mL package size: Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 22 lb.

For 3.08 mL package size: Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 44 lb.

For 4.62 mL package size: Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 88 lb.

(Note to reviewer: First Aid statements may be boxed and/or bulleted if label space allows or may be presented unboxed and unbulleted. If unboxed, First Aid statements still to be grouped near Precautionary Statements and be ordered by the most severe route of exposure.)

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 poison control center or doctor for treatment advice.
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 by the poison control center or doctor. • Do not give anything 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. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian. Individual sensitivities may occur after using any pesticide product. Consult a veterinarian immediately.

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

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, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.</p> <p>HAZARDS CONTINUED ON SIDE PANEL(S)</p>	<p>CAT WARNING ICON DO NOT USE 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 immediately.</p> <p>[CAT WARNING ICON, Min. 1.5x1.5 cm] 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 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 immediately.</p> <p>[CAT WARNING ICON, Min. 1.5x1.5 cm] 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, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.</p> <p>HAZARDS CONTINUED ON SIDE PANEL(S)</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. Do not use on dogs 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 may occur after using any pesticide product. If signs of sensitivity occur, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals.

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).
2 Giralda Farms, Madison, NJ 07940

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.

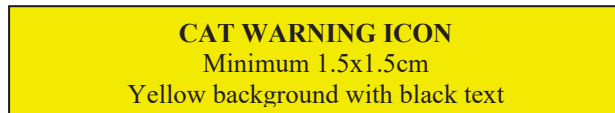
APPLICATOR LABELING STATEMENTS

ACTIVYL 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

Indoxacarb:19.53%



or

DO NOT USE ON CATS

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
Minimum 1.5x1.5cm
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

DO NOT USE ON CATS
[CAT WARNING ICON, Min 1.5x1.5cm]
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 CATS OR 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. Do not apply to dogs weighing less than 4 lb.

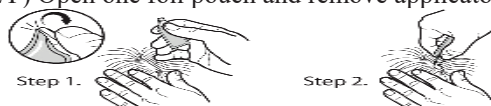
For 0.77 mL package size: Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 14 lb.

For 1.54 mL package size: Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 22 lb.

For 3.08 mL package size: Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 44 lb.

For 4.62 mL package size: Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs 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)



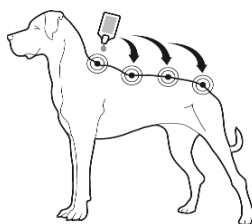
For dogs over 14 lb up to 22 lb ONLY
(For dogs over 6.6 kg up to 10 kg)
(0.77 mL size only)



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 3 (*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.

(Note to reviewer: First Aid statements may be boxed and/or bulleted if label space allows or may be presented unboxed and unbulleted. If unboxed, First Aid statements still to be grouped near Precautionary Statements and be ordered by the most severe route of exposure.)

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 poison control center or doctor for treatment advice.
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 by a poison control center or doctor.• Do not give anything 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. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian. Individual sensitivities 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, using tobacco, or using the toilet. 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. Do not use on dogs 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 may occur after using any pesticide product. If signs of sensitivity occur, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals.

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).
2 Giralda Farms, Madison, NJ 07940

LOGO Merck Animal Health

Copyright xxxx All rights reserved. xxxxxxxx

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 through 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 transmit 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. Do not apply more than once a month.
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. (Activyl® for Dogs and Puppies) (Alternate or brand name) kills fleas that may cause anemia.
9. (Activyl® for Dogs and Puppies) (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 (Activyl® for Dogs and Puppies) (alternate brand name) kills fleas
11. For the (prevention)(and)(treatment) of flea infestations on dogs (and/or) (puppies) (>) (greater than) (older than) 8 weeks and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs) 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) (>) (greater than) (older than) 8 weeks and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs) for (four)(4)(weeks)
15. One treatment prevents flea infestations (on dogs) (and/or) (puppies) (>) (greater than) (older than) 8 weeks and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs) for (one)(1)(month)
16. Protects (your dog) (and/or) (puppy) (>) (greater than) (older than) 8 weeks and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs) from fleas for (four)(4)(weeks)
17. Protects (your dog) (and/or) (puppy) (>) (greater than) (older than) 8 weeks and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs) from fleas for (one)(1)(month)
18. Monthly treatment (recommended) for optimal (control)(and)(prevention) of fleas (on your)(dog)(and/or)(puppy) (>) (greater than) (older than) 8 weeks and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs)
19. Effective monthly (control) (prevention)(and)(treatment) of fleas (on dogs) (and/or) (puppies) (>) (greater than) (older than) 8 weeks and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs)
20. Flea (control) (prevention)(and)(treatment) formulated for (dogs)(and)(puppies) (>) (greater than) (older than) 8 weeks and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs)
21. (Controls)(Treatment against)(Protects against) (blood-feeding) (by) fleas following exposure to the product.
22. Monthly treatments are (recommended) for optimal (control) (and) (prevention) of flea(s) (infestations)

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

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23. Prevents and controls flea re-infestations
 24. For optimum treatment, control and prevention of fleas (on your (pet) (dog)) monthly treatment throughout the year is recommended.
 25. (Activyl® for Dogs and Puppies) (This product) (Alternate brand name) kills all flea stages (- egg, larvae, and adult)
 26. Flea eggs and flea larvae in (the pet's) (your dog's) surroundings are killed following contact with (Activyl® for Dogs and Puppies) (alternate or brand name) treated pet.
 27. Water-resistant
 28. Waterproof
 29. (Activyl® for Dogs and Puppies) (Alternate brand name) (This product) Remains effective even after (bathing) (water immersion), (or) (exposure to rain) (or) (sunlight)
 30. (Activyl® for Dogs and Puppies) (Alternate or brand name)(This product) Remains effective after (bathing) (and) (or) (swimming)
 31. (Activyl® for Dogs and Puppies) (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. (Activyl® for Dogs and Puppies) (Alternate or brand name) (This product) remains effective against cat fleas after antibacterial shampoo treatment
 34. Once-a-month Topical Flea Treatment
 35. X Monthly Doses (with corresponding images of number of monthly applicators contained in packaging)
 36. 8 Weeks+ / >4-14 lb ONLY / TOY (packaging callouts dependent on each weight)
8 Weeks+ / >14-22 lb ONLY / S
8 Weeks+ / >22-44 lb ONLY / M
8 Weeks+ / >44-88 lb ONLY / L
8 Weeks+ / >88-132 lb ONLY / XL
 37. TOY (corresponding to 0.51 ml package size)
S (corresponding to 0.77 ml package size)
M (corresponding to 1.54 ml package size)
L (corresponding to 3.08 ml package size)
XL (corresponding to 4.62 ml package size)

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ALTERNATE MARKETING TEXT

1. Once-A-Month Topical Flea (Treatment) (Prevention) (Control) for (dogs) (and) (puppies) (>) (greater than) (older than) 8 weeks and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs)
2. (Once) monthly (a month) application (treatment) (for)(dogs) (and) (puppies) (>) (greater than) (older than) 8 weeks and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs)
3. (Reapplication at monthly intervals) (Monthly reapplications) may be appropriate depending upon (the level of flea challenge) (and) (animal sensitivities) (i.e., flea allergy dermatitis). Do not apply more than once a month.
4. X applicators
5. X monthly doses (applications)(treatments)
6. Quick drying (non-greasy)
7. Long Lasting (Fast Acting) for up to 1 month (30 days)
8. (Effective) Long-lasting protection for up to 1 month (30 days).
9. Easy to apply (spot-on) (topical) (application)(treatment)
10. Convenient (to use)(monthly use)(monthly treatment)
11. Easy (Convenient) to apply
12. Easy (spot on) (to use) application
13. (Convenient) (Single) (Spot) application
14. No noticeable odor.
15. No fragrance added
16. Formulated for dogs (and) (puppies) > 8 weeks and older and weighing more than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs)
17. Questions (or) (comments) call (1-800-Tel. Number)(or)(Tel. No.)
18. For more information call (1-800- Tel. Number) (or Tel. No.)
19. For emergencies call (1-800- Tel. Number) (or) (Tel. No.)-same as above
20. If you have any questions, call Technical Services at (1-800- Tel. Number) (or) (Tel. No.)
21. (Manufacturer) (Satisfaction) Guaranteed or your money back.

ALTERNATE MARKETING TEXT (cont'd)

22. Recommended monthly treatment for year round (control) (prevention) against fleas
23. (Control)(Treatment)(Prevention) for flea infestations
24. Protects (your) (dog) (and) (or) (puppy > 8 weeks) and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs) for (1 month)(one month)(a month) against fleas
25. (Activyl® for Dogs and Puppies) (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 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs), taken into a flea-contaminated environment.
26. Indoxacarb is from the chemical class of oxadiazine insecticides
27. (Indoxacarb is a)Voltage-dependent sodium channel blocker
28. Indoxacarb (the active) (in brand name) (in this product) (in Activyl® for Dogs and Puppies) blocks the channels that regulate the flow of sodium through the insect's nervous system.
29. (Convenient) (Single) (Spot) application that provides (control)(treatment)(protection) (of)(from)existing flea (infestations)
30. Protects against reinfestation(s) of fleas (on) (your) (dog) (puppy) (>) (greater than) (older than) 8 weeks and (weighing) greater than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs)
31. When used monthly, (Activyl® for Dogs and Puppies) (alternate brand name) (this product) breaks the flea life cycle.
32. (Activyl® for Dogs and Puppies) (Alternate or brand name) (This product) can be used on puppies (>) (greater than) (older than) 8 weeks of age and weighing more than (4 lbs) (14 lbs) (22 lbs) (44 lbs) (88 lbs)
33. Water-resistant
34. Waterproof
35. (Activyl® for Dogs and Puppies) (Alternate brand name)(This product) Remains effective (even) after (bathing) (swimming) (water immersion), (or) (exposure to rain) (or) (sunlight)
36. (Activyl® for Dogs and Puppies) (Alternate brand name)(This product) remains efficacious following (a) (shampoo treatment) (swimming) (and) (or) (exposure to rain) (or) (sunlight).
37. 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 (Activyl® for Dogs and Puppies) (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) (>) (greater than) (older than) 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 (Activyl® for Dogs and Puppies) (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

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