

773-95

02/01/2012

1/12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



FEB 01 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Patricia Sheehy
Intervet Schering-Plough Animal Health
556 Morris Avenue
Summit, NJ 07091

Dear Ms. Sheehy:

Subject: PRIA Amendment to review submitted efficacy data to support the following proposed claims: "Flea efficacy demonstrated in global field studies," "Effectively controls fleas in the home environment," "demonstrated effectiveness with dogs with FAD," "May be used with Scalibor Protector Band" ACTIVYL Tick Plus for Dogs and Puppies
EPA Registration No. 773-95
Your Submission Dated: September 20, 2011
Decision Number 455115

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable.

The efficacy studies, MRIDs 48604001-03 were reviewed and the findings were summarized in the efficacy memo dated 1/25/12 (A. Metzger). Based on the review, the only claim that is supported is "Effectively controls fleas on dogs in a home environment."

No Companion Animal Safety Study was submitted, therefore the claim "May be used with Scalibor Protector Band" is not supported.

A stamped copy of the labeling is enclosed for your records. Please submit one final printed copy of the labeling before releasing the product for shipment. If you have any questions regarding this label, please contact Autumn Metzger at (703) 305-5314 or metzger.autumn@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "John Hebert", written over a large, stylized circular flourish.

John Hebert
Product Manager 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

2/12

“Master Label for ACTIVYL® Tick Plus”:

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

FRONT PANEL

Activyl® Tick Plus

For Dogs and Puppies

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

Alternate Brand Names:

- Activyl® Tick Plus Spot-On
- Activyl® Tick Plus for Dogs or Puppies
- Activyl® Tick Plus Spot-On for Dogs and Puppies
- Activyl® Tick Plus Spot-On for Dogs or Puppies

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

- over (>)(greater than) 11 lb (pounds) and (up to) (less than or equal to) 22 lb (pounds) ONLY
- over (>)(greater than) 22 lb (pounds) and (up to) (less than or equal to) 44 lb (pounds) ONLY
- over (>)(greater than) 44 lb (pounds) and (up to)(less than or equal to) 88 lb (pounds) ONLY
- over (>)(greater than) 88 lb (pounds) and (up to)(less than or equal to) 132 lb (pounds) ONLY
- over (>)(greater than) 132 lb (pounds) ONLY

Active Ingredients:

- 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.....13.01%
- Permethrin*:
3-(phenoxybenzyl)-methyl-(±) cis, trans-3-(2,2-dichloroethenyl)-2,2-
Dimethylcyclopropanecarboxylate.....42.50%

Other Ingredients:.....44.49%
Total 100.00%

*cis/trans ratio Min. 35%(±) cis and Max. 65%(±)trans

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

SEE BACK PANEL FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

**ACCEPTED
FEB 01 2012
Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:**

() Bracket text allows for alternative presentations of the same claim. EPA. Reg. No: 773-95

BACK PANEL

CAT WARNING ICON

Permethrin-, cyphenothrin- and phenothrin-containing products:

DO NOT USE ON CATS - MAY BE FATAL
Keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately.

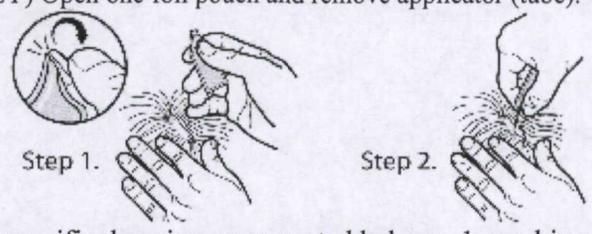
Format – same size as marketing icons
Yellow background with black text

DIRECTIONS FOR USE

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

TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

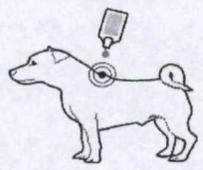
(HOW TO APPLY) Open one foil pouch and remove applicator (tube).



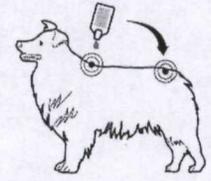
3. Graphics for specific dog sizes represented below – 1 graphic per package size



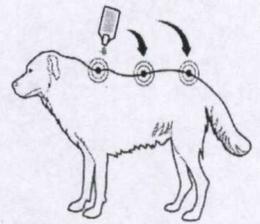
For dogs over 11 lb up to 22 lb ONLY
(For dogs more than 5.0 kg up to 10 kg)
(0.02 fl.oz.(0.5 mL) size only)



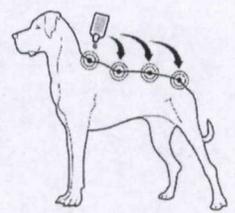
For dogs over 22 lb up to 44 lb ONLY
(For dogs over 10 kg up to 20 kg)
(0.03 fl.oz.(1.0 mL) size only)



For dogs over 44 lb up to 88 lb ONLY
(For dogs over 20 to 40 kg)
(0.07 fl.oz (2.0 mL) size only)



For dogs over 88 lb up to 132 lb ONLY
(For dogs over 40 kg up to 60 kg)
(0.14 fl.oz (4.0 mL) size only)



For dogs over 132 lb ONLY
(For dogs over 60 kg)
(0.20 fl.oz. (6.0 mL) size only)

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

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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. 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.

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.

(ALTERNATE Step 3 Directions for larger dogs:

Step 3. Apply entire contents of tube evenly to (two)(or)(three)(or)(four) spots on the back from between the shoulder blades to 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 solution on the skin. Squeeze applicator firmly applying entire contents directly to skin. Do not apply an excessive amount of solution at any one spot. Do not allow product to run off. Do not have contact with treated area (application site) until it is completely dry.)

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.

FOR EXTERNAL USE ON DOGS AND PUPPIES ONLY.

For 0.5 mL package size: Do not use on dogs or puppies under 8 weeks of age and weighing less than 11 lb.

For 1.0 mL package size: Do not use on dogs or puppies under 8 weeks of age and weighing less than 22 lb.

For 2.0 mL package size: Do not use on dogs or puppies under 8 weeks of age and weighing less than 44 lb.

For 4.0 mL package size: Do not use on dogs or puppies under 8 weeks of age and weighing less than 88 lb.

For 6.0 mL package size: Do not use on dogs or puppies under 8 weeks of age and weighing less than 132 lb.

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 a poison control center or doctor immediately for treatment advice.• Have 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	

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

Have the product container or label with you when calling a 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.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS**

CAUTION. Causes moderate eye irritation. Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with eyes, skin or 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. Consult a veterinarian before using this product on debilitated, aged, and medicated animals. Do not use on pregnant or nursing animals. Individual sensitivities, while rare, may occur after using any pesticide product. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals.

DO NOT USE ON CATS. May be toxic or potentially fatal if applied to or ingested by cats. Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided. Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harmful effect.

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 this 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. 773-95
EPA Est. No. 6175-LA-1

Net Contents: X applicator(s), each 0.02 fl.oz. (0.5 mL) {Total X fl.oz (X ml)}
X applicator(s), each 0.03 fl.oz. (1.0 mL) {Total X fl.oz (X ml)}
X applicator(s), each 0.07 fl.oz. (2.0 mL) {Total X fl.oz (X ml)}
X applicator(s), each 0.14 fl.oz. (4.0 mL) {Total X fl.oz (X ml)}
X applicator(s), each 0.20 fl.oz. (6.0 mL) {Total X fl.oz (X ml)}

Made in the USA

Intervet Inc (d/b/a Merck Animal Health). LOGO Merck Animal Health
Summit, NJ 07068
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.

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APPLICATOR/BLISTER LABELING

Activyl® Tick Plus

Cat Warning Icon or DO NOT USE ON CATS

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

over (>)(greater than) 11 lb (pounds) and (up to) (less than or equal to) 22 lb (pounds) ONLY
over (>)(greater than) 22 lb (pounds) and (up to) (less than or equal to) 44 lb (pounds) ONLY
over (>)(greater than) 44 lb (pounds) and (up to)(less than or equal to) 88 lb (pounds) ONLY
over (>)(greater than) 88 lb (pounds) and (up to)(less than or equal to) 132 lb (pounds) ONLY
over (>)(greater than) 132 lb (pounds) ONLY

Indoxacarb.....13.01%
Permethrin.....42.50%

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

0.02 fl.oz. (0.5 mL) or
0.03 fl.oz. (1.0 mL) or
0.07 fl.oz. (2.0 mL) or
0.14 fl.oz. (4.0 mL) or
0.20 fl.oz. (6.0 mL)

EPA Reg. No. 773-95
EPA Est. No. 6175-LA-1

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

Lot No:

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FOIL POUCH LABELING

DO NOT REMOVE APPLICATOR (TUBE) UNTIL READY TO USE

Activyl® Tick Plus

Cat Warning Icon

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

over (>)(greater than) 11 lb (pounds) and (up to) (less than or equal to) 22 lb (pounds) ONLY
over (>)(greater than) 22 lb (pounds) and (up to) (less than or equal to) 44 lb (pounds) ONLY
over (>)(greater than) 44 lb (pounds) and (up to)(less than or equal to) 88 lb (pounds) ONLY
over (>)(greater than) 88 lb (pounds) and (up to)(less than or equal to) 132 lb (pounds) ONLY
over (>)(greater than) 132 lb (pounds) ONLY

Indoxacarb.....13.01%
Permethrin.....42.50%

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

0.02 fl.oz. (0.5 mL) or
0.03 fl.oz. (1.0 mL) or
0.07 fl.oz. (2.0 mL) or
0.14 fl.oz. (4.0 mL) or
0.20 fl.oz. (6.0 mL)

EPA Reg. No. 773-95
EPA Est. No. 6175-LA-1

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

Lot No:

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OPTIONAL PESTICIDE CLAIMS – FRONT, BACK and/or SIDE PANELS

1. Kills fleas that may cause bartonellosis or transmit tapeworm.
2. Kills fleas that may cause (flea allergy dermatitis) (FAD).
3. Kills fleas that may cause flea allergy dermatitis, bartonellosis or transmit tapeworm.
4. (Activyl® Tick Plus) (alternate brand name) provides control of vectors which may transmit disease.
5. (Activyl® Tick Plus) (alternate brand name) kills fleas that (may cause anemia) (may transmit tapeworms).
6. 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® Tick Plus) (alternate brand name) kills fleas.
7. For the (prevention)(and)(treatment) of flea and tick infestations on (dogs)(and)(puppies) 8 weeks and older for (four)(4)(weeks) (one)(1)(month).
8. Once monthly application is recommended. Do not apply more than once a month.
9. Prevents and controls re-infestations. Pesticidal. Excellent flea mortality.
10. Controls and prevents flea and tick infestations on dogs) (and/or)(puppies) for (four)(4)(weeks) for (one)(1)(month). Do not apply more than once a month.
11. (Prevents) (and) (protects) against (re-)infestation (of fleas and ticks) for (four)(4)(weeks).
12. (Prevents) (and) (protects) against (re-)infestation (of fleas and ticks) for (one)(1)(month).
13. One treatment prevents (flea) (and) (tick) (infestations) (on)((dogs)(and)(puppies) 8 weeks and older for (four)(4)(weeks) for (one)(1)(month).
14. Protects (your dog) (and/or) (puppy) 8 weeks and older from (fleas) (and) (ticks) for (four)(4)(weeks) (one)(1)(month).
15. Provides ongoing protection against fleas and ticks for (four)(4)(weeks) (one)(1)(month).
16. Monthly treatment recommended for optimal (control)(and)(prevention)(of fleas and ticks) (on your) (dog)(and)(puppy) 8 weeks and older.
17. Effective monthly (control) (prevention)(and)(treatment) of (fleas) (and)(tick) (on) (dogs)(and)(puppies) 8 weeks and older.
18. Kills ticks for (four)(4)(weeks) (one)(1)(month)
19. (Flea) (and) (tick) (control) (prevention)(and)(treatment) formulated for (dogs)(and)(puppies) 8 weeks and older
20. (Controls)(Treatment against)(Protects against) (by) fleas and ticks.
21. Monthly treatments are recommended for optimal (control) (and) (prevention) of (flea)(and)(tick) (infestations). Do not apply more than once a month.

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

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22. Killing fleas and ticks is important in the prevention of disease transmission by these insects and the parasites (vectors) they may carry
23. After application, (Activyl® Tick Plus)(Alternate brand name)(This product) (spreads over the dog's body to provide (full body) (all over) protection against fleas and ticks
24. Contains permethrin, an effective insecticide/acaricide that provides efficacy against ticks
25. Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis and bartonellosis.
26. Kills ticks that including those that may (cause) (transmit) Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, anaplasmosis, tularemia and Southern tick-associated rash illness (STARI).
27. Kills Brown Dog ticks (*Rhipicephalus sanguineus*) (that may transmit ehrlichiosis, Rocky Mountain spotted fever and babesiosis) American dog ticks (*Dermacentor variabilis*) (that may transmit Rocky Mountain spotted fever), Deer ticks (*Ixodes scapularis*) (that may transmit Lyme disease) and Lone Star ticks (*Amblyomma americanum*) (that may transmit ehrlichiosis, rickettsiosis - Rocky Mountain spotted fever and Southern tick-associated rash illness (STARI) and tularemia (for one month)
28. Kills ticks that may transmit (Lyme Disease) (babesiosis) (ehrlichiosis) (Rocky Mountain spotted fever) (anaplasmosis).
29. Kills ticks that may cause tick paralysis.
30. (Fleas)(and)(Ticks) can be a year-round problem!
31. (Activyl® Tick Plus) can be used year-round.
32. Monthly use breaks flea life cycle
33. Provides relief from biting fleas
34. Stops flea feeding, followed (closely) by paralysis and death.
35. (Activyl® Tick Plus)(Alternate brand name)(This product) Remains effective against fleas and ticks even after (swimming) (water immersion), (or) (exposure to rain) (or) (sunlight).
36. (Activyl® Tick Plus)(Alternate brand name)(This product) remains efficacious following (swimming) (and) (or) (exposure to rain) (or) (sunlight).
37. For optimum treatment (control) and prevention of flea and tick infestations, year round treatment is recommended.
38. (Prevents)(annoying)(bothersome)(nuisance) (blood-feeding) (by)(biting fleas)(by) (killing)(and) (biting fleas) for (up to)(four)(4)(weeks)(one)(1)(month). Prevents flea larval development.
39. Larval flea stages in (the pet's) (your dog's) surroundings are killed following contact with (Activyl® Tick Plus)(Alternate brand name) treated pets.

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ALTERNATE MARKETING TEXT

1. (Activyl® Tick Plus)(Alternate brand name)(This product) is highly effective in killing fleas for four weeks. After ingestion, enzymes of susceptible insects metabolize indoxacarb into its paralyzing and lethal metabolite. This process is known as bioactivation. The product is convenient and easy to apply.
2. Intended to be sold by veterinarians.
3. Intended to be dispensed (and)(or) sold through (by) licensed veterinarians and to their clients for pets under a direct vet-client-patient relationship.
4. Product availability intended through licensed veterinarians.
5. Indoxacarb (an active)(in Activyl® Tick Plus)(in brand name)(in this product) blocks the channels that regulate the flow of sodium through the insect's nervous system.
6. Through the metabolic activation process (bioactivation), the insect's enzymes remove the carbomethoxy group, converting indoxacarb (an active in) (Activyl® Tick Plus) (brand name) to the more insecticidally active compound.
7. Indoxacarb is an active ingredient from the oxadiazine chemical class.
8. (Activyl® Tick Plus)(Alternate brand name)(This product)(It) may also be used to (control)(prevent) infestation on flea-free (dogs)(and)(or)(puppies 8 weeks and older) taken into a flea-contaminated environment.
9. (Indoxacarb is a) voltage-dependent sodium channel blocker.
10. Permethrin is a synthetic pyrethroid
11. Permethrin is a voltage-dependent sodium channel blocker.
12. Permethrin is an adulticide
13. (Reapplication at monthly intervals) (Monthly reapplications) may be appropriate depending upon (the level of flea challenge) (and) (animal sensitivities)(i.e., flea allergy dermatitis).
14. X (applicators)(monthly doses) (applications)(treatments)
15. (Long Lasting) (Effective) (Protection) for 1 month (30 days) (Specifically) formulated for dogs (and)(puppies 8 weeks and older)
16. (Convenient)(Easy)(to apply)(to use) (spot-on) (topical) (application)(treatment).
17. Fragrance free
18. No noticeable odor
19. Questions (or)(comments) call (1-800-Tel. Number)(or)(Tel. No.)

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

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20. For more information call (1-800- Tel. Number)(or Tel. No.)For emergencies call (1-800- Tel. Number)(or)(Tel. No.)
 21. If you have any questions, call Merck Animal Health Technical Services at (1-800- Tel. Number)(or)(Tel. No.)
 22. Shampooing decreases efficacy.
 23. Flea and tick control for today's ectoparasite challenges.
 24. (Manufacturer) (Satisfaction) Guaranteed
 25. Effectively controls fleas and ticks on dogs in a home environment.

12/12

NEXT DOSE STICKERS/ TREATMENT REMINDER (prototype)

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

Use these handy stickers to help remember when your pet’s next application is due. When you use the last tube in this package, call your veterinarian immediately to order more (product) (Activyl® Tick Plus)(alternate brand name).

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

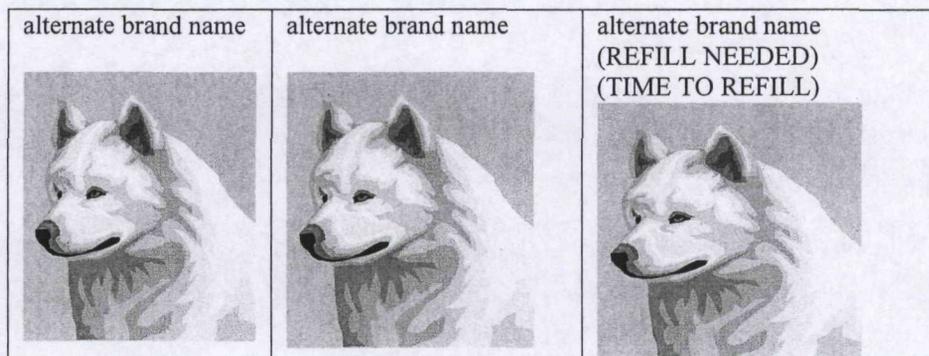
Alternate text

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

Attach these (stickers)(reminders) to your (wall)(desk) calendar (daily planner) on the days of the first application, and on the same date for each of 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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