


83399-1

12/05/2006

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 <p style="text-align: center;"> U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505C) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460 </p> <p style="text-align: center;"> NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration <small>(under FIFRA, as amended)</small> </p>	EPA Reg. Number: 83399-1	Date of Issuance: DEC - 5 2006
	Term of Issuance: Conditional	
	Name of Pesticide Product: SVP4	
Name and Address of Registrant (include ZIP Code): Summit VetPharm, LLC 400 Kelby Street Fort Lee, NJ 07024		
<p>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.</p> <p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered 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.</p> <p>This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) and (B) provided that you:</p> <ol style="list-style-type: none"> 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4. 2. Submit the following data: One year storage stability (830.6317) and corrosion characteristics (830.6320) studies. These studies can be run concurrently. We have received and reviewed the interim studies for these two requirements. The final report must be submitted within 6 months from today's date. 		
Signature of Approving Official: <i>Rita Kumar</i>	Date: DEC - 5 2006	

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3. Make the following label changes:

- a. Add the phrase "EPA Registration Number 83399-1".
- b. Remove the parentheses from "over 7 weeks of age" on page one, and from the optional marketing statements. This must be a mandatory restriction, not an optional statement. Rephrase this statement as follows: "For dogs and puppies over 7 weeks of age **and** weighing....."
- c. Add the following to the beginning of second and forth sentences in the Limited Warranty and Limitation of Damages statement: "To the extent consistent with applicable law, ..."

d. Revise the Storage and Disposal statement as follows:

Do not contaminate water, food, or feed by storage and disposal.
Storage: Store in a cool, dry place. Protect from freezing.
Disposal: If empty, do not reuse the container. Place in trash or offer for recycling if available. If partially filled, call your local.....

- e. Delete the label claims "Convenient topical treatment specially formulated for dogs who enjoy the outdoors" and "Specially formulated for dogs that love the outdoors". These are heightened efficacy claims and must be deleted, or rephrased to read "Convenient topical treatment formulated for dogs that enjoy the outdoors" and "Formulated for dogs that love the outdoors".
- f. Delete the label claim "SVP1 also contains the insect growth regulator pyriproxyfen that acts to prevent the development of all flea stages for at least one month" or provide efficacy data to document this claim.
- g. The following label claims are not supported by the data and must be deleted: "SVP1 is stored in the superficial layers of the dog's skin, providing ongoing protection against fleas, ticks and mosquitoes for at least one month" and "SVP1 is stored in the lipids of the dog's skin, providing ongoing protection against fleas, ticks and mosquitoes for at least one month".
- h. The label claim "Begins working within minutes of application and kills up to 99% of fleas within 6 hours" must be rephrased as follows: "Kills up to 99% of fleas within 6 hours".
- i. The label claim "Repels and kills mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp), including those that may transmit West Nile virus and heartworm (Dirofilaria immitis) for at least one month" must be rephrased as follows: "Repels and kills mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp), including those that may transmit heartworm (Dirofilaria immitis)".
- j. The label claim "Works fast to kill the vectors of Lyme disease, Rocky Mountain

spotted fever, babesiosis, ehrlichiosis, bartonellosis, West Nile virus and heartworm" must be rephrased as follows: "Kills vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, and heartworm.

- k. Statements such as "Satisfaction guaranteed" or "Guaranteed effective for at least one month" need to be qualified (*e.g.*, or your money back), or must be removed from the label.
- l. Revise "Monthly treatment is required..." to "Monthly treatment is recommended..."
- m. Delete reference to dinotefuran working synergistically with permethrin or provide efficacy data to demonstrate synergistic effect.
- n. Delete the statement, "Gentle enough..." and any other similar claims. Such safety claims are not permitted.
- o. Delete the statement, "Well-tolerated at up to 5 times the recommended dose" and any other similar claims like "wide margin of safety". Such safety claims are not permitted.
- p. Delete terms like "highly" effective, "excellent" efficacy, "works fast", "acts fast", "fast knockdown", "Fast", "Fast-acting", "the most resistant", "the most stubborn" and similar open ended heightened efficacy claims.
- q. Add the qualifier word "may" to all claims referring to "killing vectors or transmitter of", *e.g.*, "kills the vectors that may transmit.....", or "Kills ticks which may carry disease".
- r. Delete all references to flea allergy dermatitis, hepatozoonosis, and tick paralysis. These disease prevention claims are not substantiated with submitted efficacy data.
- s. Change "Kills ticks that can...." to "Kills ticks that may...." in several optional marketing statements.
- t. Delete all references to "minimizing risk of disease transmission" and "killing those ticks which attach to the dog". These claims are not substantiated with submitted efficacy data.
- u. In the Hazards to Domestic Animals statement, delete reference to calling the company if signs of animal sensitivity occur. PR Notice 96-6 requires that a veterinarian should be called if signs of sensitivity occur. Use the following language: "Sensitivities may occur after using ANY pesticide product for pets. 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." Delete the sentence "If signs of individual sensitivity occur.....and persist"

- v. Delete the phrase "begins working in minutes", or provide efficacy data to document this claim.
- w. Delete all references to "novel", "novel proven" and "specially formulated". The word "new" may be used for a period of six months from the date of registration.
- x. Qualify the statement "Protects against 4 types of ticks, 3 types of mosquitoes, all stages of fleas", as adult mosquitoes etc., and by listing the species, which must only be the species that were tested in submitted efficacy data.
- y. Delete the Questions and Answers section. This does not belong on a label. This can accompany the product, however you must ensure the claims do not exceed those accepted on the label.
- z. Delete any reference to use of the product more than once in 30 days unless recommended by a veterinarian. This is an implied animal safety claim and cannot be allowed.
- aa. Delete the statement, "Well-tolerated at up to 5 times..." or any other similar claim. This is an implied animal safety claim, and cannot be allowed.
- bb. Combine and rephrase the two statements (# 5 and # 6) on top of page 4.
- cc. Revise the statement "Protects against all stages of the flea life cycle" to read as follows: "Regular use protects against.....".

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. Submit two copies of the final printed label before you release the product for shipment.

A stamped copy of the label is enclosed for your records. A copy of the efficacy review is also enclosed for your perusal.

Sincerely,

Rita Kumar

Rita Kumar
Insecticide Rodenticide Branch
Registration Division (7505C)
E-mail: kumar.rita@cpa.gov

Enclosures (2)

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FRONT PANEL OF OUTER BOX

SVP4

(Optional marketing claims—front and side panels/continued on pages 5-7)

- For dogs and puppies (over 7 weeks of age) weighing over 55 lbs.
- Fast effective monthly treatment of fleas, ticks and mosquitoes
- Repels and kills fleas, ticks and mosquitoes for at least one month
- Prevents development of fleas, flea eggs, pupae and larvae for one month or more
- Kills fleas in 6 hours
- For dogs that enjoy the outdoors
- Remains effective after bathing and swimming
- Easy, spot on application
- Guaranteed effective for at least one month

SIDE A

ACTIVE INGREDIENTS:

Dinotefuran	14.85%
Pyriproxyfen.....	1.51%
OTHER INGREDIENTS	83.64%
TOTAL	100.00%

SIDE B

ACTIVE INGREDIENT:

Permethrin	45.00%
OTHER INGREDIENTS	55.00%
TOTAL	100.00%
100.00%	

KEEP OUT OF REACH OF CHILDREN

CAUTION: See package insert for (directions for use), (precautionary statements), (first aid,) (and) (ingredients.)

DO NOT USE ON CATS
[ICON OF CAT IN CIRCLE WITH SLASH THROUGH]

with COMMENTS
in EPA Letter Dated:
DEC - 5, 2006
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
As amended, for the pesticide
Registered under EPA Reg. No.
83399-1

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BACK PANEL OF OUTER BOX

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS [OR] [AND] PUPPIES OVER THE AGE OF 7 WEEKS (OVER 7 WEEKS OLD) (7 WEEKS OF AGE OR OLDER)

DO NOT USE THIS PRODUCT ON CATS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Causes moderate eye irritation. Harmful if swallowed. Harmful if absorbed through skin. Remove and wash contaminated clothing before reuse. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs only

Do not use on puppies less than 7 weeks old

Do not use this product on debilitated, aged, medicated, pregnant or nursing animals or animals known to be sensitive to pesticide products without first consulting a veterinarian. Sensitivity, such as slight transitory redness of the skin at the site of application, may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of individual animal sensitivity occur and persist, contact your veterinarian (or call) [company] [at] [telephone number]. Have the product container or label with you when calling (company) (or) your veterinarian for advice.

DO NOT USE ON CATS

Due to their unique physiology and inability to metabolize certain compounds, this product must not be used on cats. If applied to a cat, or ingested by a cat that actively grooms a recently treated dog, this product may have serious harmful effects. If this occurs contact your veterinarian immediately.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

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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. Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice
If swallowed:	Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.
If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Precaución al consumidor: si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the User: If you cannot speak English, do not use this product until the label has been fully explained to you.)

HOW TO APPLY:

1. **USE ONLY ON DOGS. Do not use on cats or other animals.**
2. Remove applicator from package. For dogs over 95 lbs., use two applicators.
3. Hold applicator with applicator point facing upward and tear off (cut off) (bend) (break off) tip along perforation (score) (mark) (line) (as shown below).

GRAPHICS DEPICTING HOW TO OPEN PACKAGE/APPLICATOR

4. The dog should be standing or in a comfortable position for easy application.
5. Apply the product evenly to four spots along the dog's back, beginning between the shoulder blades and continuing in the order shown in the diagram below.

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6. Part the hair down to the level of the skin and slowly apply the product until the applicator is completely empty. Avoid superficial application to the animal's hair.

[GRAPHICS DEPICTING TREATMENT OF ANIMAL]

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

7. Discard empty applicator as outlined in Storage and Disposal.
8. Repeat every month, or as needed. Do not reapply more frequently than every 30 days unless recommended by your veterinarian.
9. For optimum treatment, control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes, (all) year-round treatment is recommended.

STORAGE AND DISPOSAL

Storage: Do not contaminate water, food or feed by storage and disposal. Store in a cool, dry place. Protect from freezing. If empty, do not reuse the container. Place in trash or offer for recycling if available. If partially filled, call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused products down any indoor or outdoor drain.

NET CONTENTS: X applications (applicators), each 0.16 fl. oz. (4.7 mL) [Total X fl. oz., X mL]

EPA Reg. No. 83399-R
EPA Est. No.

[Made in the USA (by)] [Distributed by:]
Summit VetPharm, LLC
Fort Lee, NJ 07024

PACKAGE INSERT (full label text plus additional copy)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Seller warrants that the material conforms to the chemical parameters of the US EPA registration and the label. Seller makes no warranty, express or implied, other than indicated on the label. Buyer and user assume all risk of use and handling of this material when such use and handling are contrary to the label instructions. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

ALTERNATE MARKETING TEXT

- Protects for at least one month
- Satisfaction guaranteed
- Fast-acting
- Long-lasting
- Prevents re-infestation for up to one month
- Monthly treatment is required for optimal control and prevention of fleas, ticks and mosquitoes
- Begins working within minutes of application
- Once monthly application
- X applicators
- X monthly doses (applications) (treatments)
- Quick drying, non-greasy and water-resistant
- Easy to apply spot-on application
- Convenient, easy to apply
- Fragrance (odor) free
- Convenient to use
- Water-resistant
- Convenient (easy to apply) topical treatment
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Convenient topical treatment specially formulated for dogs who enjoy the outdoors
- Specially formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors

- Fast kill of fleas, ticks and mosquitoes is important in the prevention of disease transmission by these parasites
 - (Only) available from licensed veterinarians
 - Well-tolerated at up to 5 times the recommended dose
 - *Specially formulated for dogs [and puppies 7 weeks or older] [and] [over 55 lbs.]*
 - Gentle enough for puppies from 7 weeks of age
 - After application, SVP4 spreads naturally over the dog's body to provide (full body) (all-over) protection against fleas, ticks and mosquitoes
 - SVP4 is stored in the superficial layers of the dog's skin, providing ongoing protection against fleas, ticks and mosquitoes for at least one month
 - SVP4 contains dinotefuran, a novel neonicotinoid insecticide with a fast knockdown, which is highly specific to the nervous system of insects, and has a wide margin of safety in mammals. Dinotefuran kills fleas within 6 hours
 - SVP4 also contains permethrin, a highly effective insecticide/acaricide that provides excellent efficacy against ticks and mosquitoes and acts synergistically with dinotefuran against fleas.
 - SVP4 also contains the insect growth regulator pyriproxyfen that acts to prevent the development of all flea stages for at least one month.
 - Approximately 95% of the flea population in a household infestation is immature flea stages that live in the dog's environment.
 - SVP4 is stored in the lipids of the dog's skin, providing ongoing protection against fleas ticks and mosquitoes for at least one month
 - Questions or comments—please call (tel. no.)
 - For more information call (tel. no.)
-
- Works fast to kill the vectors of Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, West Nile virus and heartworm
 - Kills fleas, ticks and mosquitoes before they lay eggs
 - Repels and kills fleas, ticks and mosquitoes
 - Fast, effective monthly treatment of fleas, ticks and mosquitoes
 - Easy, fast, effective control of fleas, ticks and mosquitoes that lasts at least 1 month
 - Protects against 4 types of ticks, 3 types of mosquitoes, all stages of fleas
-
- Kills over 95% of fleas in 6 hours and up to 100% in 12 hours
 - Acts fast to kill fleas that may transmit disease, including bartonellosis
 - Kills fleas before they lay eggs
 - Kills *and repels* fleas before they lay eggs
 - Kills fleas that may cause flea allergy dermatitis
 - The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with SVP4 rapidly kills fleas and may reduce the incidence of this condition.
 - Regular use breaks the flea life cycle
 - Protects against all stages of the flea life cycle

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- Prevents development of all flea stages for at least 1 month
- Begins working within minutes of application and kills up to 99% of fleas within 6 hours

- Kills and repels ticks within 24 hours
- Repels and kills ticks that (cause) (transmit) Lyme disease
- Repels and kills ticks including those that may transmit Lyme disease
- Acts fast to kill ticks that may cause disease, including Lyme disease
- Repels and kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, hepatzoonosis, ehrlichiosis, or cause tick paralysis
- Repels and kills brown dog ticks (*Rhipicephalus spp*), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes scapularis*) and Gulf Coast ticks (*Amblyomma maculatum*)
- Repels and kills ticks including Deer ticks (vector of Lyme disease), American dog ticks (vector of Rocky Mountain spotted fever), Brown dog ticks (vector of ehrlichiosis) and Gulf Coast ticks (that cause tick paralysis) for at least one month
- Kills ticks that can carry and transmit the organism which causes Lyme disease
- Kills ticks that can carry and transmit babesiosis
- Kills ticks that can carry and transmit Ehrlichia
- Kills ticks [in 24-48 hours] before they can transmit Lyme disease
- Kills ticks[in 24-48 hours] before they can transmit Ehrlichia
- Repels ticks before they can attach to dogs and take a blood meal
- Repels and kills ticks, which may transmit disease
- Kills ticks before they can lay eggs
- Kills ticks which carry disease
- Repels many ticks before they can attach [and kills those ticks which attach to the dog] [minimizing the risk of disease transmission
- Minimizes the risk of disease transmission by repelling ticks before attachment and killing those ticks which attach to the dog.

- Repels and kills mosquitoes (*Culex spp*, *Ochlerotatus spp*, *Aedes spp*), including those that may transmit West Nile virus and heartworm (*Dirofilaria immitis*) for at least one month
- Repels and kills 90-100% of mosquitoes for at least one month

- Novel proven treatment technology for the most resistant flea infestations
- Novel proven treatment technology for the most stubborn flea infestations
- Recommended for use in an integrated flea management system

QUESTIONS & ANSWERS (Q&A)

What is SVP4?

SVP4 is an easy-to-apply monthly spot-on treatment that protects dogs against fleas, ticks and mosquitoes for at least one month. It:

- Kills fleas within 6 hours, before they lay eggs
- Repels and kills ticks that may spread Lyme disease, ehrlichiosis, babesiosis and Rocky Mountain spotted fever
- Repels and kills mosquitoes that may spread West Nile virus and heartworm
- Remains effective after bathing and swimming

SVP4 is effective against 4 species of ticks, 3 kinds of mosquitoes and all species and stages of the flea life cycle.

How quickly does SVP4 kill fleas, ticks, and mosquitoes?

SVP4 works in 2 ways to help protect your pet against annoying fleas, ticks and mosquitoes. It *repels* these parasites so fewer actually land on your pet. And SVP4 begins to kill the fleas, ticks, and mosquitoes that land on your dog within minutes. Results show that, with SVP4, 96% of fleas are killed within 6 hours and up to 100% are killed within 12 hours of application. SVP4 also works fast to kill mosquitoes and ticks ensuring your pet is rapidly protected from these disease-carrying parasites.

How does SVP4 work?

SVP4 contains a special ingredient that is proven to repel fleas, ticks and mosquitoes, so that they avoid contact with your dog. It also kills fleas, ticks and mosquitoes by causing the parasites' nervous systems to become impaired.

After SVP4 is applied, it spreads on the surface of the skin to provide whole body protection. The ingredients are fast-drying, so that your dog can play with other pets in your household after just a few minutes. If you have a cat, do not allow the cat to lick your dog immediately after treatment.

How is SVP4 used?

Just one application, once a month, provides your dog with protection against fleas, ticks and mosquitoes for at least 30 days. SVP4 is quick-drying, non-greasy and water-resistant, so you can play with your dog after just a few minutes.

Is SVP4 easy to use?

Yes! Once a month, you simply apply a pre-measured dose from the applicator tube by parting the hair of the dog's coat and squeezing the tube. (For dogs under 20 lbs, the product should be applied at a single spot between the shoulder blades.) (For dogs 21-55 lbs, apply the product evenly along the dog's back at 3 spots as shown on the label.) (For dogs over 55 lbs apply the product at 4 spots,) as shown on the label. That's all there is to it. Your veterinarian will ensure that you have the right dose for your dog.

Will SVP4 still work if my pet goes swimming or takes a bath?

Yes! SVP4 is proven effective even after bathing and swimming.

How often should I use SVP4?

A single treatment will protect your dog against fleas, flea eggs and larvae, ticks, and mosquitoes for at least one month. For optimum prevention of infestation, year-round treatment is recommended.

Is SVP4 safe enough to use year-round?

Yes! SVP4 can be safely used all year to protect against fleas, ticks, and mosquitoes. This can be especially

helpful in parts of the country where fleas, ticks, and mosquitoes are a year-round problem. Ask your veterinarian if you should treat your dog in the winter months.

Safety studies show SVP4 was well tolerated, even when administered to dogs at five times the normal dose. You can be confident that SVP4 is gentle when used at the recommended dose.

Is SVP4 safe to use on puppies?

SVP4 is safe to use on puppies over 7 weeks of age.

Does SVP4 offer complete flea protection?

SVP4 protects against all species of fleas. It works on all stages of the flea life cycle, killing adult fleas, flea eggs and larvae. Breaking the flea life cycle may help reduce the risk of flea allergy dermatitis.

Which ticks does SVP4 protect against?

Studies have shown that SVP4 repels and kills the four species of ticks tested – deer ticks (*Ixodes scapularis*), American dog ticks (*Dermacentor variabilis*), Brown dog ticks (*Rhipicephalus sanguineus*) and Gulf Coast ticks (*Amblyomma maculatum*).

Where can I purchase SVP4?

SVP4 is only available from your veterinarian.

How does SVP4 reduce the risk of disease?

If fleas, ticks or mosquitoes bite your pet, they can transmit diseases. The longer they remain on your pet, the greater the chance your dog will get sick. SVP4 helps prevent disease transmission by repelling many fleas, ticks, and mosquitoes, making them avoid your dog, and by quickly killing any parasites that actually land on your dog.

What diseases can be spread by ticks, mosquitoes, and fleas?

Ticks can spread Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, hepatozoonosis and babesiosis. They can also cause tick paralysis. Mosquitoes can spread West Nile virus and heartworm disease. Fleas can spread tapeworm and Cat Scratch fever (bartonellosis), and may also cause anemia.

Ask your veterinarian which diseases are common where you live. You may also want to talk to your veterinarian before taking your dog on vacation—this will ensure your pet is protected against any diseases in your vacation spot.

Why is repelling ticks and mosquitoes important?

Ticks and mosquitoes that don't land on your dog can't bite him. And, if they don't bite your pet, they can't spread disease.

How do I know if my dog is at risk for ticks?

Your veterinarian can help you determine if your dog is at risk from tick infestation. Your dog's risk is higher 1) if your pet has been bitten by a tick in the past, 2) if tick-borne diseases are common where you live, 3) if your dog spends time hiking, hunting or camping with you in wooded areas or grassy meadows, 4) if your pet comes in contact with deer, rodents, raccoons or other wild animals, 5) if your yard has tall grass, thick shrubs or mulch that has not been treated.

What can happen if my pet gets fleas?

It depends on the degree of infestation, and on your dog's reaction to the parasite. For example, some dogs may experience hair loss, itching, and discomfort. Others develop an allergic reaction to the flea bites, called flea allergy dermatitis (FAD), which can cause more severe hair loss and can be very uncomfortable. FAD may

persist for several weeks after the fleas have been killed. Secondary skin infections, tapeworms and anemia are also medical problems that can be associated with fleas. Severe flea infestation may lead to significant skin disease, anemia or even death, especially in young animals. SVP4 rapidly eliminates the risk of any flea-related problems by killing 96% of existing fleas within 6 hours, and preventing the development of all flea stages for at least one month.

How long will it take to get rid of my flea infestation?

Prevention is the key to a flea-free household. That's why it's best to use SVP4 once a month, year round. If your dog has an existing flea infestation, SVP4 will rapidly kill any adult fleas landing on your pet and also prevents development of all immature flea stages (which live in your house or yard) for at least one month, helping to quickly eradicate the infestation. If the infestation is heavy, your veterinarian may recommend that you treat other pets in the household as well as your home and yard, in addition to treating your dog. Do not use SVP4 on cats.

Can SVP4 be used on cats?

No. Due to their unique physiology and inability to metabolize certain compounds, SVP4 should not be used on cats. If you apply the product to your cat by mistake, please contact your veterinarian immediately.

I treated my dog with SVP4 but I still see fleas in my home – why?

When your dog is infested with fleas, most of the flea population is actually made up of immature fleas (eggs, larvae and pupae) which live in your home or yard. SVP4 acts quickly to kill any adult fleas on your pet before they lay eggs. However, immature fleas in the environment may continue to develop for several weeks after you treat your dog, causing you to still see fleas in your home. Monthly treatment with SVP4 will break the flea life cycle and help to eradicate the household infestation. You should also treat all other dogs and cats in the household with an appropriate SVP product and, for particularly heavy household infestations, your veterinarian may recommend that you use a product directly in your home or yard.

What if I still see fleas after using SVP4?

SVP4 acts fast to kills fleas within 6 hours and protects against re-infestation for at least one month. Since the majority of the flea population (eggs, larvae and pupae) actually live in your home or yard and not on your pet, you may occasionally see newly emerged adult fleas on your pet. However, rest assured that SVP4 will act quickly to kill the fleas before they lay eggs.

My dog is on medications (is pregnant/nursing); can I still use SVP4?

SVP4 is specially formulated for dogs and puppies over 7 weeks. It acts superficially on the coat and skin of your pet and is not absorbed systemically. Ask your veterinarian for advice before using SVP4 on sick, debilitated, aged or pregnant or nursing dogs.

Can SVP4 be used on other animals, such as rabbits or ferrets?

SVP4 has not been tested on animals other than dogs and puppies. SVP5 is specifically formulated and available for cats. Consult your veterinarian for advice on the best products to use for parasite control in other pets.

I already applied a different flea control product; can I still use SVP4?

SVP4 contains a new treatment called dinotefuran which has been shown to be highly effective against fleas and has a high safety margin in mammals. It acts superficially on the coat and skin of your dog to rapidly kill fleas. When changing from a different flea control product, SVP4 may effectively be applied as soon as the protection period of the other product is over. If you wish to use SVP4 sooner, please consult your veterinarian before application.

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SVP4: EPA FILE SYMBOL 83399- R
DRAFT REVISED PROPOSED LABELING
Date: 9/22/06

Are there any side effects from SVP4?

No significant treatment related events were seen in safety studies carried out with SVP4.

What about flea resistance?

SVP4 is a new kind of treatment effective against even the most resistant flea population. Yet it is gentle enough for year round monthly use so that your dog or puppy can remain free from fleas.

What is flea resistance?

After years of successive use of the same product the fleas may become resistant to the treatment (product) (insecticide), so it no longer delivers to your dog the effective level of protection that it initially provided.

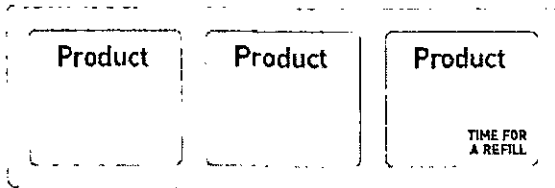
NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

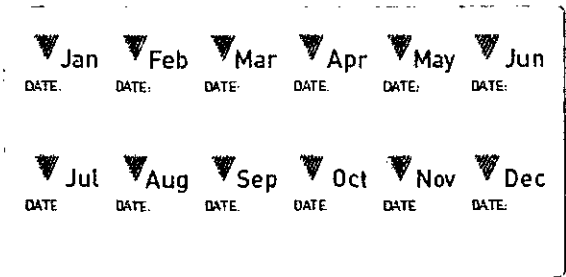
NEXT DOSE STICKERS AND REMINDER CALENDAR

It can be hard to remember when your dog's due for its next dose of Product. So we developed these tools to help you keep track of every dose. When you use the last tube in this package, call your veterinarian to order more Product.

Attach these stickers to your wall calendar or day planner on the date you give the first dose of Product, and then place another sticker on the same date for each of the next two months.



To use the calendar, simply write in the dates you are planning to use Product. Then, peel off the backing and place it in a hard-to-miss location.



16/16

SVP4: EPA FILE SYMBOL 83399- R
DRAFT REVISED PROPOSED LABELING
Date: 9/22/06

APPLICATOR LABELING

SVP4

KEEP OUT OF REACH OF CHILDREN

CAUTION
READ ENTIRE LABEL BEFORE USE

SIDE A

Dinotefuran 14.85%
Pyriproxyfen..... 1.51%

SIDE B

Permethrin..... 45.00%

0.16 fl. oz. (4.7 mL)

DO NOT USE ON CATS [ICON]

EPA Reg. No. 83399-E
EPA Est. No. TBD

Lot # (*designation will identify producing establishment*)