

83399-6

08/16/2013

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

AUG 16 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Alicia Henk
Director Pharmaceutical Development and Regulatory Affairs
Ceva Animal Health
8735 Rosehill Rd., Suite 300
Lenexa, KS 66215

Dear Ms. Henk:

Subject: Label amendment - spot-on risk mitigation and in response to companion animal study review
SVP7
EPA Registration Number 83399-6
Your submissions dated 3/14/2013, and 7/30/2013
OPP tracking decision number D476745

Revised label dated July 30, 2013, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is accepted subject to the comments listed below:

1. Submit the final printed label with a clear picture of a dog in each weight range for the product as packaged on the front panel of the label, plus other graphics and pictures.
2. This registration is now time-limited and expires two years from the date of this letter.
3. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning [January 1, April 1, July 1, or October 1, whichever date most closely follows the date of the letter].

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kaitlin Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number

Product name (brand name)

Lot #

Where purchased: internet, store, veterinarian

Active Ingredient(s)

Weight range for product

Date on which incident occurred. (mm/dd/yyyy)

State in which the incident occurred. (standard 2 letter abbreviation)

Registrant case #

Species: dog, cat, other (specify)

Breed: (as reported by pet owner)

Age: months or years

Sex: M, F, or neutered

Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other

Body System: neurological, dermatological, GI, respiratory, ocular, other

Major signs noted with separate column for each sign, using standard terminology

Time to Onset: (hours, days)

Treated by veterinarian: yes or no

First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor

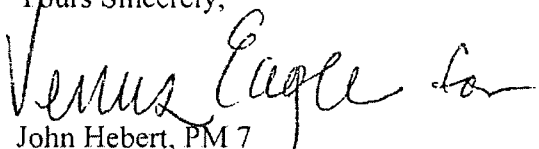
Outcome: died, recovered, still treated, unknown

5. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

Submit one copy of your final printed labeling as required in comment number 1 above. If you have any questions, please contact Rita Kumar at (703) 308-8291, or kumar.rita@epa.gov.

Yours Sincerely,

 John Hebert, PM 7
 Insecticide-Rodenticide Branch
 Registration Division (7505P)

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AMENDED LABELING
Date: August 9, 2013

"Master Label"
(This master label includes label text for different size packages and application rates specific to the pet's age and body weight)

FRONT PANEL OF OUTER BOX

SVP7 for Dogs

Picture of dog/puppy according to weight range

Alternate Brand names;

- Vectra 3D** for Dogs and Puppies 5.0 - 20 lbs., over 8 weeks of age [1.6 ml]
- Vectra 3D** for Dogs and Puppies 21-55 lbs., over 8 weeks of age [3.6 ml]
- Vectra 3D** for Dogs 56-95 lbs [4.7 ml]
- Vectra 3D** for Dogs over 95 lbs [8.0ml]
- SimpleGuard 3 for Dogs and Puppies 5.0 - 20 lbs., over 8 weeks of age [1.6 ml]
- SimpleGuard 3 for Dogs and Puppies 21-55 lbs., over 8 weeks of age [3.6 ml]
- SimpleGuard 3 for Dogs 56-95 lbs [4.7 ml]
- SimpleGuard 3 for Dogs over 95 lbs. [8.0ml]

ACCEPTED
AUG 16 2013
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:

EPA. Reg. No: 83399-6

[FOR DOGS & PUPPIES – Use only on dogs weighing 5.0 to 20 lbs. and 8 weeks or older]
[FOR DOGS & PUPPIES – Use only on dogs weighing 21-55 lbs. and 8 weeks or older]
[FOR DOGS & PUPPIES – Use only on dogs weighing 55-95 lbs. and 8 weeks or older]
[FOR DOGS & PUPPIES – Use only on dogs weighing over 95 lbs. and 8 weeks or older]

Repels and Kills for one month

- Fleas
- Ticks
- Mosquitoes
- (Biting & Sucking) Lice
- Mites (excluding mange mites)
- Biting & Sand Flies

(Optional marketing claims—front or back or side panels/see on pages 6-14)

ACTIVE INGREDIENTS:

Dinotefuran	4.95%
Pyriproxyfen.....	0.44%
Permethrin	36.08%
OTHER INGREDIENTS	58.53%
TOTAL	100.00%

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KEEP OUT OF REACH OF CHILDREN

WARNING

Net Contents: XXX fl oz
XXX Doses [each dose, xxx fl oz (xxx mls)]

Front, back, side and/or insert language

See package insert for directions for use, precautionary statements and first aid

Cat prohibition icon (registrant believes alternate colors may be necessary for contrast since different colors for each weight class to avoid confusion by clinic and owners of multiple pet owners. Box colors are teal, blue, purple and red. Registrant agree to have contrast to insure clarity.)

DO NOT USE ON CATS

[ICON OF CAT IN CIRCLE WITH SLASH THROUGH PLACED LOWER RIGHT CORNER – FRONT PANEL (1.5 cm X 1.5 cm)]

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS [OR] [AND] PUPPIES OVER THE AGE OF 8 WEEKS (OVER 8 WEEKS OLD) (8 WEEKS OF AGE OR OLDER)

PRECAUTIONARY STATEMENTS

Hazards to Humans;

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

Hazards to Domestic Animals;

Do not use this product on debilitated, aged, medicated, pregnant or nursing dogs or dogs known to be sensitive to pesticide products without first consulting a veterinarian.

For external use on dogs only

Do not use this product on cats

Use only on dogs [and/or] puppies over the age of 8 weeks (over 8 weeks) (8 weeks of age or older) 0.054 fl.oz (1.6 ml), 0.122 fl.oz (3.6 ml), 0.159 fl.oz (4.7 ml), 0.27 fl.oz (8.0 ml)

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Side Effects: Monitor your dog after application. Individual sensitivity, such as slight transitory redness, erythema, itching -pruritus- or other signs of discomfort at the site of application, may occur after using ANY pesticide product for dogs. If signs of sensitivity occur, bathe your dog with mild soap or shampoo and rinse with large amounts of water. If signs of individual animal sensitivity occur and persist, contact your veterinarian. Gastrointestinal signs such as vomiting or diarrhea have also been reported, if these signs occur, consult your veterinarian or call us at 1-800-999-0297. Have the product container or label with you when calling your veterinarian for advice.

[CAT PROHIBITION ICON - CAT IN CIRCLE WITH SLASH THROUGH (1.5 cm X 1.5 cm) Back Panel Lower Right]

DO NOT USE ON CATS-MAY BE FATAL. Due to their unique physiology and inability to metabolize certain compounds this product must not be used on cats. Keep cat away from treated dogs for 24 hours. If applied to a cat, or ingested by a cat that actively grooms a recently treated dog, contact your veterinarian immediately.

FIRST AID	
If in eyes:	Hold eye open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a poison control center or doctor, for treatment advice.
If swallowed:	Call a poison control center or doctor, for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.
If on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15–20 minutes. If skin appears irritated after rinsing call a poison control center or doctor, or 1-800-999-0297 or after 6pm EST call 1-888-426-4435 immediately for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may contact 1-800-999-0297 weekdays between 9am and 6pm EST or 1-888-426-4435 for emergency medical treatment information.	

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 Restrictions: USE ONLY ON DOGS. Do not use on cats or other animals. Do not have contact or allow children to have contact with treated areas until treatment is completely dry.**
2. Remove applicator tube from package.
3. The dog should be standing or in a comfortable position for easy application.
4. Holding the (applicator) tube upright, pointing away from face, place thumb and index finger around the applicator tip under the large disk. With other hand, grasp the stem of applicator tip above smaller disk. Press down firmly on small disk until both disks meet, piercing the seal. (See illustration)

GRAPHICS DEPICTING HOW TO OPEN PACKAGE/APPLICATOR

5. Using the tip of the applicator, part the hair down to the level of the skin (between the shoulder blades) and slowly apply the product (to one spot) (as shown below) (onto the skin, squeezing the applicator (tube) until empty.) Avoid superficial application to the dog's hair.

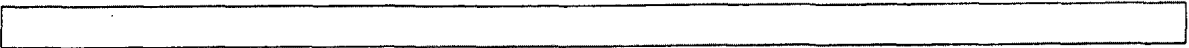
OR:

5. [For dogs weighing 5.0 to 20 lbs] (Using the tip of the applicator, part the hair down to the level of the skin and slowly) apply the product as one spot, as shown in the diagram above, onto the skin, squeezing the applicator tube until empty.] (Avoid superficial application to the dog's hair.)

5. [For dogs weighing 21 to 55 lbs or For dogs weighing 56 to 95 lbs] (Using the tip of the applicator, part the hair down to the level of the skin and slowly) apply the product evenly to three spots along the dog's back, beginning between the shoulder blades and continuing in the order shown in the diagram below, squeezing the applicator (tube) until empty. (Avoid superficial application to the dog's hair.)

OR:

5. [For dogs weighing over 95 lbs:] (Using the tip of the applicator, part the hair down to the level of the skin and slowly) apply the product evenly to four spots on the dog's back, beginning between the shoulder blades and continuing in the order shown in the diagram below, squeezing the applicator (tube) until empty. (Avoid superficial application to the dog's hair)



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[GRAPHICS DEPICTING TREATMENT OF ANIMAL]

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

OR

5. (For all dog weights) Using the applicator tip part the hair at the base of the tail and begin applying the product onto the skin in a continuous line from the base of the tail along the center of the back all the way up to the shoulder blades, as shown in the diagram, squeezing the applicator tube until it is empty. (Avoid superficial application to the dog's hair)
6. Discard empty applicator (tube) as outlined in the Storage and Disposal section.
7. Repeat every month, or as recommended by your veterinarian.
8. For optimal treatment control and prevention of adult and immature flea stages, ticks, mosquitoes, lice, mites, biting flies, and sand flies (all) year-round treatment is recommended.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.
 Storage; Store in a cool, dry place. Protect from freezing.
 Disposal; Place in trash or offer for recycling if available. Never place unused products down any indoor or outdoor drain.

NET CONTENTS: X applications (applicators), each (0.06, 0.12, 0.16, 0.3 fl. oz). (1.6, 3.6, 4.7, 8.0 mL) Example: 3 single dose (applicators)(package) 1.6 ml (0.6 fl.oz. total 0.18 fl.oz) [Total 0.18 0.36, 0.48, 0.9 fl. oz., 4.8, 10.8, 14.1, 24.0 mL]

(Volume varies with size of animal for which package is intended and number of applicators per package. Product may be packaged in 1, 2, 3, 4, 6, 8, 9, 12, 24, 36, 72 or 144 applicators per package. Total volume will correspond to number of applicators.)

EPA Reg. No. 83399-6
EPA Est. No.

[Made in the USA (by)] [Sold by:]
Ceva Animal Health, LLC
8735 Rosehill Road
Lenexa, KS 66215

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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. To the extent consistent with applicable law, 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. To the extent consistent with applicable law, 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 (for use on front or side or back panels)

- Protects for one month
- Performance (satisfaction) guaranteed or (Ceva Animal Health) will supply replacement product
- Effective monthly prevention and treatment of fleas, ticks, and mosquitoes
- Repels and kills fleas, ticks and mosquitoes for one month
- Prevents development of adult and immature flea life stages for one month
- Dinotefuran provides efficacy against fleas, ticks and mosquitoes.
- Pyriproxyfen is an insect growth regulator which prevents development of all flea stages.
- Picture of Dog (or Puppy appropriate to weight class)
- Prevents development of adult and immature flea-life stages for 30 days

- Using the (patented) (Trademark) applicator, SVP7 is specially designed to spread over the dog's body providing effective control of fleas, ticks, and mosquitoes for thirty days (four weeks, one month).
- Formula for (your) dog(s)
- Kills fleas in 6 hours
- Remains effective after bathing and swimming
- Easy, spot-on (topical) application
- (Patented) applicator tip (Trademark) for easy application directly to the skin
- Guaranteed effective for one month
- Satisfaction guaranteed or your money back (Ceva ICON) (Please call (contact) our professional staff at xxx-xxx-xxxx if you have any questions or comments about SVP7)
- SVP7 contains the insecticide dinotefuran, a neonicotinoid with knockdown effect. Permethrin is an effective insecticide/acaricide that works with dinotefuran and pyriproxyfen to kill and repel fleas, ticks and mosquitoes

- Prevents re-infestation (of fleas/f ticks) for one month
- Monthly treatment is recommended for control and prevention of fleas, ticks and mosquitoes

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- Once monthly application
- X applicators
- X monthly dose(s) (applications) (treatments)
- Quick-drying, non-greasy and water-resistant (waterproof)
- Easy to apply spot-on application
- Convenient, easy to apply
- Fragrance (odor) free
- Convenient to use
- Water-resistant
- Quick drying
- Non-greasy
- Convenient (easy to apply) topical treatment
- Convenient (easy to apply) topical treatment [with (patented) applicator tip] that allows application down to the skin
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Remains effective even after bathing
- Remains effective after exposure to rain and sunlight
- Still works after bathing, swimming or exposure to sunlight
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Available from licensed veterinarians
- Sold by veterinarians
- Tested on puppies from 8 weeks of age
- After application, SVP7 spreads naturally over the dog's body to provide (full body) (all-over) protection against fleas, ticks and mosquitoes
- SVP7 provides ongoing protection killing fleas, ticks and mosquitoes for one month (30 days)
- SVP7 (contains dinotefuran, a neonicotinoid insecticide) with onset of flea knockdown in less than 2 hours
- SVP7 also contains permethrin, an effective insecticide/acaricide that combines with dinotefuran to provide efficacy against fleas, ticks and mosquitoes
- SVP7 contains the insect growth regulator pyriproxyfen that acts to prevent the development of all flea stages for one month (30 days).
- *Immature flea stages are a major component of flea infestation, SVP7 contains pyriproxyfen which controls immature flea stages.*
- Questions or comments—please call (tel. no.) (or e-mail us at contact.us@ceva.com)
- For more information call (tel. no.) (or e-mail us at contact.us@ceva.com)
- For emergencies call (tel. no)

- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis and heartworm disease
- Repels and kills fleas, ticks and mosquitoes
- Easy, fast, effective control of fleas, ticks and mosquitoes that lasts 1 month

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- Kills [4 types (species) of] ticks (*Rhipicephalus* spp, *Dermacentor variabilis*, *Ixodes* spp, *Amblyomma maculatum*), [3 types (species) of] mosquitoes (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp), and all stages of fleas
- Kills fleas including those that may transmit bartonellosis and tapeworm disease
- Monthly use kills (controls) all stages of the flea life cycle
- Kills fleas that may cause flea allergy dermatitis (FAD)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with SVP7 rapidly kills fleas that may cause FAD.
- SVP7 kills fleas that may cause Flea Allergy Dermatitis (FAD)
- Monthly use (of SVP7) breaks the flea life cycle
- Kills (controls) all stages of the flea life cycle
- Prevents development of all flea stages for 1 month (30 days)
- Repels and kills ticks that may transmit Lyme disease
- Repels and kills ticks including those that may transmit Lyme disease
- Repels and kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, hepatozoonosis and anaplasmosis
- 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 for one month
- Kills ticks that may carry and transmit the organism which causes Lyme disease
- Kills ticks that may carry and transmit babesiosis
- Kills ticks that may carry and transmit Ehrlichia
- Repels ticks before they can attach to dogs and take a blood meal
- Repels many ticks before they can attach and kills those ticks which attach to the dog

- Repels and kills ticks so they fall off treated dogs and die

- Repels and kills mosquitoes (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp) which may vector heartworm (*Dirofilaria immitis*) for one month
- Proven treatment technology for flea infestations
- Proven treatment technology for the control of fleas, ticks and mosquitoes
- Recommended for use in an integrated flea management system which includes treatment of both the dog and environment
- Pyriproxyfen control and attacks (all stages of) immature fleas
- Pyriproxyfen the insect growth regulator found in SVP7 stops the development of immature fleas
- Puppy pack (24, 36, 72 and 144 packages only) [1.6 and 3.6ml packages only]
- Dog (canine) pack (24, 36, 72 and 144 packages only)
- Veterinary pack, Ceva pack (24, 36, 72 and 144 packages only)

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- Effective monthly treatment of fleas, ticks and mosquitoes
- Effective monthly treatment of fleas (ticks)(mosquitoes)
- Repels and kills fleas (ticks)(mosquitoes)
- Monthly treatment is recommended for control (and prevention) of fleas, ticks and mosquitoes
- SVP7 provides ongoing protection against fleas, ticks and mosquitoes for one month
- SVP7 contains permethrin an effective insecticide/acaricide that combines with dinotefuran to provide efficacy against fleas, ticks and mosquitoes
- Protects against all types of Ixodes species attacking dogs
- Kills Ixodes scapularis, Ixodes pacificus and Ixodes ricinus
- Effective control of fleas, ticks and mosquitoes
- Kills [4 types (species) of ticks (Rhipicephalus spp, Ixodes spp, Dermacentor variables, Amblyomma maculatum, Amblyomma americanum), [3 types (species of)] mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp)
- Repels and kills fleas that may cause anemia
- Kills fleas that may cause anemia
- Repels fleas that may cause anemia
- Prevents flea infestation which may lead to anemia
- Kills the listed pests that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, anaplasmosis and heartworm disease
- Repels and kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis and anaplasmosis
- Repels and kills mosquitoes that may transmit heartworm disease
- Repels and kills Brown dog ticks (Rhipicephalus spp), Deer ticks (Ixodes spp), American dog ticks (Dermacentor variabilis) Lone Star ticks (Amblyomma americanum) and Gulf Coast ticks (Amblyomma maculatum)
- Repels and kills Deer ticks (Ixodes scapularis, Ixodes ricinus, Ixodes pacificus)
- Long lasting – one month - flea, tick and mosquito control for your dog
- SVP7 kills more than adult fleas you see, it controls immature flea stages
- Kills all life stages of ticks
- SVP7 repels and kills fleas, ticks, mosquitoes
- Prevents all flea stages from developing
- SVP7 kills not only adult fleas, but also breaks the flea life cycle by preventing development of immature fleas (may include diagram of flea life cycle) for 30 days (one month) (4 weeks)
- Illustration of flea life cycle
- Kills [4 types (species) of ticks (Rhipicephalus spp, Dermacentor variabilis, Ixodes spp, Amblyomma spp), [3 types (species) of mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp) all stages of fleas for 30 days (one month) (4 weeks).
- Controls [4 types (species) of ticks (Rhipicephalus spp, Dermacentor variables, Ixodes spp, Amblyomma americanum, Amblyomma maculatum and Amblyomma americanum), [3 types (species) of mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp) all stages of fleas for one month (30 days) (4 weeks).

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- Repels and kills ticks including Deer ticks (vector of Lyme disease) American dog ticks (vector of Rocky Mountain spotted fever), Brown dog tick (vector of ehrlichiosis) and Gulf Coast ticks and Lone Star ticks (vector of hepatozoonosis) for one month (4 weeks) (30 days)
 - Repels and kills Brown dog ticks (*Rhipicephalus* spp), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp) and Gulf Coast ticks (*Amblyomma maculatum*) and Lone Star ticks (*Amblyomma americanum*) for one month (4weeks) (30 days)
 - Kills *Amblyomma americanum* (Lone Star ticks) and *Amblyomma maculatum* (Gulf Coast ticks) for 4 weeks (for one month) (for 30 days)
-
- Maintains residual efficacy after bathing and swimming
 - Single application lasts 4 weeks (one month) (30 days)
 - Controls the flea life cycle at all (immature) life stages for 4 weeks (30 days) (one month)
 - Repellency and protection against fleas, ticks and mosquitoes for 4 weeks (30 days) (one month)
 - Repellency against fleas, ticks, mosquitoes, lice, mites and sand flies for 4 weeks (30 days) (one month)
-
- Contains the proven effective topical, dinotefuran, for effective flea control
 - Contains the proven effective topical pyriproxyfen, for control of immature fleas
 - Pyriproxyfen, the insect growth regulator (found in SVP7), controls (stops) the development of immature fleas
 - Contains the proven effective topical repellent permethrin (for control of fleas, ticks, mosquitoes, lice, mites and biting & sand flies)
 - Repels fleas, ticks, mosquitoes, sand flies, lice and mites (excluding mange mites)
 - Repels ticks
 - Repels fleas
 - Repels mosquitoes
 - Kills sand flies
 - Repels sand flies
 - Kills (biting & sucking) lice
 - Repels lice
 - Kills mites
 - Repels mites (excluding mange mites)
 - Repels (and kills) lice which may cause pruritus, erythema, (crusting and scaling)
 - Repels (and kills) mites (excluding mange mites) that may cause dandruff, alopecia and pruritus
 - Repels (and kills) biting & sand flies which may inflict irritating bites
 - Repels (and kills) fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and biting & sand flies
 - Repels (and kills) (annoying) (bothersome) (nuisance) biting & sand flies
 - SVP7 is indicated for the prevention and treatment of fleas, ticks, mosquitoes, biting & sand flies, lice and mites (excluding mange mites) on dogs over 8 weeks of age
 - For the treatment and prevention of flea infestation
 - For the control of all stages of flea infestation

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- One treatment prevents further flea infestation for 30 days (4 weeks) (one month)
 - Kills larval stages of fleas in the dog's environment
 - Prevent all immature flea stages in the dog's environment from developing
 - Controls the development of all immature flea stages in the environment
 - Controls existing flea infestations by rapidly killing adult fleas and preventing development of immature flea stages
 - Kills fleas that may serve as an intermediate host for tapeworms (*Dipylidium caninum*)
 - Stops existing flea infestations by killing adult fleas
 - Prevents flea eggs from hatching
 - Prevents larval stages from developing
 - Effectively (and efficiently) breaks the flea life cycle
 - Effectively targets all (life) stages of fleas (and ticks)
 - Repels and kills mosquitoes that may transmit vector borne disease
 - Prevents blood feeding by mosquitoes
 - Repels (and kills) [(annoying) (bothersome) (nuisance) sand flies and biting flies
 - 6 way protection, repels (and kills) fleas, ticks, mosquitoes, lice, biting & sand flies and mites (excluding mange mites)
 - Repels (and kills) [(biting) (chewing) lice
 - Repels mites (excluding mange mites) and prevents further infestation
 - Helps to relieve your dogs discomfort by controlling flea, tick, mite (excluding mange mites) and lice infestations
 - SVP7 controls flea infestation that may lead to painful skin irritation and bacterial infection
 - Illustration of flea life cycle
 - Illustration of tick life cycle
 - Illustration of mosquito life cycle
 - Illustration of sand fly life cycle
 - Illustration of mite life cycle
 - Illustration of louse life cycle
 - Illustration of flea
 - Illustration of tick
 - Illustration of mosquito
 - Illustration of sand fly
 - Illustration of mite
 - Illustration of louse
 - Illustration of biting fly
 - Illustration of biting fly life cycle
 - Repels (and kills) biting flies which may inflict irritating bites
 - Prevents fly strike
 - Controls fly strike
 - Repels (and kills) fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and biting & sand flies
 - Repels (and kills) (annoying) (bothersome) (nuisance) biting & sand flies

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- SVP7 is indicated for the prevention and treatment of fleas, ticks, mosquitoes, sand flies, lice and mites (excluding mange mites) on dogs over 8 weeks of age
 - Kills biting flies
 - Repels biting flies
 - Repels fleas, ticks, mosquitoes, fire ants, biting & sand flies, lice and mites (excluding mange mites)
 - Repellency against fleas, ticks, mosquitoes, lice, mites (excluding mange mites) for 4 weeks (30 days) (one month)
 - Helps to relieve your dog's discomfort by controlling fleas, ticks, mites (excluding mange mites), biting flies, and lice infestations
 - Repels and kills mosquitoes and biting & sand flies that may transmit vector borne disease
 - Repels and kills sand flies that may transmit leishmaniasis
 - Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, leishmaniasis and heartworm disease
 - Repels and kills sand flies that may transmit leishmaniasis
 - Monthly treatment is recommended for control (and prevention) of fleas, ticks, lice, mites (excluding mange mites), biting & sand flies and mosquitoes
 - Results indicate that SVP7 repels and prevents biting flies from blood feeding on dogs
 - Controls infestations of chewing lice
 - Kills and repels mosquitoes which may transmit West Nile virus
 - Kills and repels mosquitoes which may transmit disease
 - Reduces biting fly strike
 - Reduces flea feeding
 - Continues to kill and repel fleas and ticks after shampooing
 - Triple powered formula for control of fleas, ticks, mosquitoes, flies, mites and lice
 - Prevents re-infestation of fleas, ticks and chewing lice
 - Kills chewing lice
 - Kills attached ticks when applied to dog with pre-existing infestation
 - Using the (patented) (Trademark) applicator, SVP7 is specially designed to spread naturally over the dog's body providing effective control of fleas, ticks, lice, mites (excluding mange mites) and mosquitoes for thirty days (four weeks, one month).
 - Kills fleas that may cause flea allergy dermatitis and flea bite dermatitis
 - SVP7 works on multiple sites of the nervous system of fleas & ticks
 - Kills the listed vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, leishmaniasis, tularemia and heartworm disease
 - Kills biting flies
 - Repels biting flies
 - Contains the proven effective topical repellent, permethrin (for control of fleas, ticks, mosquitoes, lice, mites (excluding mange mites), biting flies (and sand flies))
 - 11-way protection against fleas, flea eggs, larvae, pupae, ticks, mosquitoes, sand & biting flies, biting & sucking lice, mites (excluding mange mites)

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- Reduced flea feeding means reduced likelihood of transmission of vector borne disease
- Limited feeding reduces likelihood of anemia, irritation, flea allergy dermatitis and transmission of disease
- Repellency against fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and sand flies for 4 weeks (30 days) (one month)
- (Regular use) (monthly use) protects your dog against all flea stages
- SVP7 for dogs susceptible to flea allergy dermatitis (FAD)
- Begins reducing flea feeding in 5 minutes
- For year round control apply SVP7 monthly year round for optimum control of fleas, ticks, mosquitoes, flies, lice and mites.
- Persistent (sustained) efficacy for (one month) (thirty days)
- Kills newly emerged fleas before they lay eggs
- Contains (free) calendar (reminder) stickers
- Monthly year round (use) (treatment) can help your dog stay happy and protected
- Helps (outdoor) dogs stay protected from fleas, ticks, mosquitoes, sand flies, biting flies, biting & sucking lice, mites (excluding mange mites)
- Available from (Ceva authorized) (Seller authorized) (approved) (endorsed) (certified) (qualified) veterinarians. (Ceva) (Seller) may take appropriate (legal) action against any person not so authorized involved in the sale of this product.
- This product has been authorized for sale by (Ceva)(Seller) exclusively through veterinarians (in the context of an established veterinarian/client/patient relationship). (Ceva) (Seller) may pursue appropriate (legal) action against any person not so authorized involved in the sale of this product.
- Sold by (Ceva authorized) (Seller authorized) (approved) (endorsed) (certified) (qualified) veterinarians. (We)(Ceva)(Seller) (company name) may take appropriate (legal) action if the product is sold by an unauthorized person.
- Sold by (authorized) (approved) (endorsed) (certified) (qualified) veterinarians. (Seller) (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.
- Available from (authorized) (approved) (endorsed) (certified) (qualified) veterinarians. Seller markets this product only to (authorized) (approved) (endorsed) (certified) (qualified) veterinarians, who have established (veterinary client relationship) (veterinary patient relationship) (veterinary client patient relationship). Sale or marketing of this product by (unauthorized) (not approved) (non-qualified) persons could results in appropriate action by the (manufacturer) (Ceva) (company name)
- Available from (Ceva authorized) (Seller authorized) (approved) (endorsed) (certified) (qualified) veterinarians.
- (Ceva) (Seller) may take appropriate (legal) action against any person not so authorized involved in the sale of this product.
- Available from licensed veterinarians. (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.
- (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.
- Sold by veterinarians. (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.

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- Sale or marketing of this product by (unauthorized) (not approve) (non-qualified) persons could result in appropriate action by the (manufacturer) (Ceva) (company name).

NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

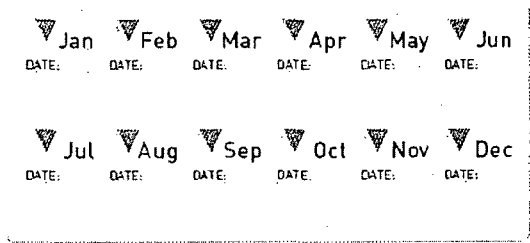
NEXT DOSE STICKERS AND REMINDER CALENDAR

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.



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APPLICATOR LABELING

SVP7 for Dogs 5.0 - 20 lbs., over 8 weeks of age [1.6 ml]
SVP7 for Dogs 21-55 lbs., over 8 weeks of age [3.6 ml]
SVP7 for Dogs 56-95 lbs. [4.7 ml]
SVP7 for Dogs over 95 lbs. [8.0ml]

Vectra 3D for Dogs and Puppies 5.0 - 20 lbs., over 8 weeks of age [1.6 ml]
Vectra 3D for Dogs and Puppies 21-55 lbs., over 8 weeks of age [3.6 ml]
Vectra 3D for Dogs 56-95 lbs [4.7 ml]
Vectra 3D for Dogs over 95 lbs [8.0ml]

SimpleGuard 3
for Dogs and Puppies 5.0 - 20 lbs., over 8 weeks of age, [1.6 ml]
SimpleGuard 3
for Dogs and Puppies 21-55 lbs., over 8 weeks of age, [3.6 ml]
SimpleGuard 3
for Dogs 56-95 lbs. [4.7 ml]
SimpleGuard 3
for Dogs over 95 lbs. [8.0ml]

KEEP OUT OF REACH OF CHILDREN

WARNING
READ ENTIRE LABEL BEFORE USE

Dinotefuran4.95%
Pyriproxyfen.....0.44%
Permethrin.....36.08%

X fl. oz. (X mL)
Use only on dogs & puppies over 8 weeks of age weighing [insert wt range] lbs
DO NOT USE ON CATS [ICON]

EPA Reg. No. 83399-6
EPA Est. No. TBD

Lot # (designation will identify producing establishment)