



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

EPA Reg. Number:

83399-9

Date of Issuance:

12/3/19

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 12/17/2021

Name of Pesticide Product:

SVP8 for Cats

Name and Address of Registrant (include ZIP Code):

Katy Hernandez
 Regulatory Specialist
 Ceva Animal Health, LLC
 8735 Rosehill Road
 Lenexa, KS 66215

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Sincerely,

Gene Benbow, Product Manager 7
 Invertebrate & Vertebrate Branch 3

Date:

12/3/19

Registration Division (7505P) Office of Pesticide Programs	
---	--

EPA Form 8570-6

2. The Agency has found your company to be in compliance with the terms and conditions for the subject product and is extending the two-year registration restriction. This registration is time-limited and expires 12/17/2021.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in Agency letter dated 9/30/2011
4. You are required to comply with the data requirements described in the DCI identified below:
 - a. Dinotefuran GDCI-044312-1147 issued on 3/1/2013

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

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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

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

- Basic CSF dated 1/25/2007

If you have any questions, please contact Scott Campbell at Campbell.Scott@epa.gov or at (703) 347-0479.

“Master Label”

This master label includes label text for different size packages and application rates specific to the pet’s age and body weight. Text that appears in braces {} are information to the EPA, but will not be printed. Text that appears in brackets [] are optional.

FRONT PANEL OF OUTER BOX

{The word cat will be at least 75% in height of the largest letter in the primary brand name. A large clear picture of a cat in the respective weight range will be on the front panel of the label.}

SVP8 for Cats

Alternate Brand Names:

[Vectra for Cats] [Vectra Plus for Cats] [Vectra Excel for Cats] [Vectra Dual for Cats] [Vectra 2C for Cats] [Vectra Duo for Cats] [Vectra II for Cats] [Vectra 2 for Cats] [Vectra Gold for Cats] [Vectra Shield for Cats] [SimpleGuard for Cats]
Over 9 lbs {1.2ml dose}

[Vectra for Cats and Kittens] [Vectra Plus for Cats and Kittens] [Vectra Excel for Cats & Kittens] [Vectra Dual for Cats & Kittens] [Vectra 2C for Cats & Kittens] [Vectra Duo for Cats & Kittens] [Vectra II for Cats & Kittens] [Vectra 2 for Cats & Kittens] [Vectra Gold for Cats & Kittens] [Vectra Shield for Cats and Kittens] [SimpleGuard for Cats & Kittens]
2 to 9 lbs[,] [and] over 8 weeks of age {0.8ml dose}

[FOR CATS & KITTENS – use only on cats and kittens 2 to 9lbs and over 8 weeks of age] [FOR CATS & KITTENS – use only on cats over 9lbs and over 8 weeks of age]

Effective monthly control of[:] adult fleas, [flea] eggs, [flea] larvae and [flea] pupae

[Optional marketing claims—front or back or side panels/continued on pages 4-8]

ACTIVE INGREDIENTS:

Dinotefuran.....	22.00%
Pyriproxyfen.....	3.00%
OTHER INGREDIENTS.....	75.00%
TOTAL.....	100.00%

**KEEP OUT OF REACH OF CHILDREN
WARNING**

See package insert for complete Directions For Use, Storage and Disposal, and other information.

**Net Contents: XXX fl oz
XX Doses [each dose, xxx fl oz (xx ml)]**

[Ceva logo] [picture of applicator tube]
[pictograms of flea and flea larvae]

BACK PANEL OF OUTER BOX

READ ENTIRE LABEL BEFORE EACH USE

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 or doctor for treatment advice
If swallowed:	Call a poison control center or doctor immediately for treatment advice. Have the 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 by mouth to an unconscious person.
If on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center, doctor, or 1-800-999-0297 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 for emergency medical information.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

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

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats and kittens [weighing] 2 to 9lbs and over 8 weeks of age {0.8 ml dose}.

For external use only on cats [weighing] over 9 lbs and over 8 weeks of age {1.2 ml dose}

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.

Side Effects: Monitor your cat after application. Individual sensitivity, such as slight transitory redness, erythema, scratching, pruritus or other signs of discomfort at the site of application, may occur after using ANY pesticide product for cats. If signs of sensitivity occur, bathe your cat 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 or other side effects 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.

DIRECTIONS FOR USE

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

RESTRICTIONS:

- FOR EXTERNAL USE ONLY.
 - Do not have contact or allow children to have contact with treated areas until treatment is completely dry.
 - Do not apply more than one tube per treatment.
- See package insert for complete Directions For Use.*

EPA Reg. No. 83399-9
EPA Est. No. XXX-XX-XX

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

[For additional information, contact us at 1-800-999-0297 [or contact.us@ceva.com]]
[Vectra and Vectra logo are registered trademarks of Ceva Animal Health, LLC.]
[SimpleGuard is a registered trademark of Vicar Operating, Inc.]
[recycling symbol] [recyclable package]
[Ceva art codes]
[lot # / sku #]

SIDE PANELS OF OUTER BOX

SVP8 for Cats

lot # / sku #
barcode
[1, 2, 3, 4, 6, 8, 9, 12, 24, or 36 Doses]
[ceva logo]

PACKAGE INSERT

SVP8 for Cats

{The above brand names will be package in the weight ranges below}

2 to 9 lbs[,] [and] over 8 weeks of age {0.8ml dose}

Over 9 lbs {1.2ml dose}

{Package insert will list only one weight range based on the package dose volume.}

Effective monthly control of[:] adult fleas, [flea] eggs, [flea] larvae and [flea] pupae

[Optional marketing claims—front or back or side panels/continued on pages 4-8]

ACTIVE INGREDIENTS:

Dinotefuran.....22.00%

Pyriproxyfen.....3.00%

OTHER INGREDIENTS.....75.00%

TOTAL.....100.00%

**KEEP OUT OF REACH OF CHILDREN
WARNING**

READ ENTIRE LABEL BEFORE EACH USE

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 or doctor for treatment advice
If swallowed:	Call a poison control center or doctor immediately for treatment advice. Have the 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 by mouth to an unconscious person.
If on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center, doctor, or 1-800-999-0297 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 for emergency medical information.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

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

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats and kittens [weighing] 2 to 9lbs and over 8 weeks of age {0.8 ml dose}.

For external use only on cats [weighing] over 9 lbs and over 8 weeks of age {1.2 ml dose}

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

DIRECTIONS FOR USE

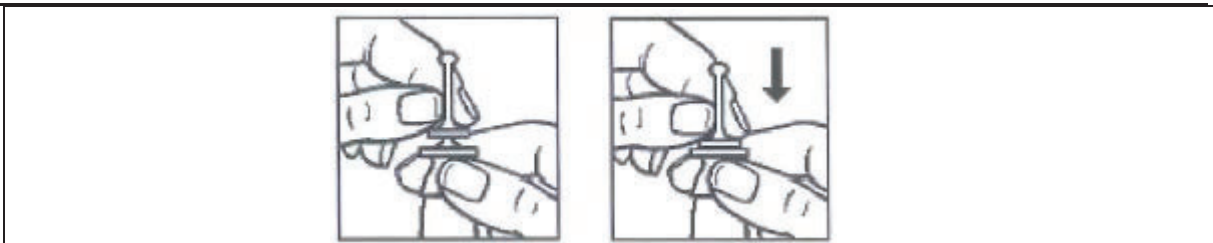
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. [Precaución al consumidor: si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the User: If you cannot speak English, do not use this product until the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

RESTRICTIONS:

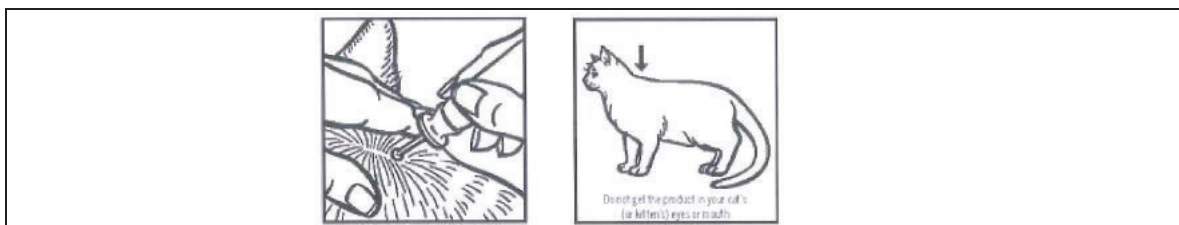
- FOR EXTERNAL USE ONLY.
- Do not have contact or allow children to have contact with treated areas until treatment is completely dry.
- Do not apply more than one tube per treatment.
- Do not allow children to apply this product.
- Use only on cats.
- Do not allow your cat to ingest this product.

HOW TO APPLY:

1. Ensure your cat is dry before applying the product, and ensure your cat remains dry for 24 hours after application. The cat should be standing or in a comfortable position for easy application.
2. Remove the applicator tube from the package.
3. Holding the applicator tube upright, pointing away from you and your cat's face, place your thumb and index finger around the applicator tip under the large disk. With the other hand, grasp the stem of the applicator tip above the small disk. Press down firmly on the small disk until both disks meet, piercing the seal. (See illustration)



4. Part the hair down to the level of the skin and slowly apply the product at the base of the cat's [and/or kitten's {0.8 ml dose}] head until the applicator tube is [completely] empty, as shown in the diagram below. Avoid superficial application to the animal's hair. Do not get the product in your cat's eyes or mouth.



5. Discard empty applicator tube as outlined in the Storage and Disposal section.
6. Repeat every month [30 days, 4 weeks], or as recommended by your veterinarian.
7. For optimal treatment, control and prevention of [adult] fleas, flea eggs, flea larvae and [flea] pupae, year-round monthly application is recommended.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Store in a cool, dry place. Protect from freezing.

PESTICIDE DISPOSAL AND CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available. **If partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[NET CONTENTS: XXX fl oz (XXX ml)]

[[1] [2] [3] [4] [6] [8] [9] [12] [18] [24] [36] [dose(s)],[applications],[applicators]]

[each 0.027 fl oz (0.8 ml)]

[each 0.041 fl oz (1.2 ml)]

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

EPA Reg. No. 83399-9
EPA Est. No. XXX-XX-XX

[Made in the USA (by)] [Sold by:] [Manufactured for][and][Distribution by][Distributed by]
Ceva Animal Health, LLC
8735 Rosehill Road
Lenexa, KS 66215
[For additional information, contact us at 1-800-999-0297 or contact.us@ceva.com]

[recycling symbol] [recyclable package]
[Vectra and Vectra logo are registered trademarks of Ceva Animal Health, LLC.]

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Seller warrants that the material conforms to the chemical parameters of the U.S. EPA registration and the label. Seller makes no warranty, express or implied, other than indicated on the label or as required by applicable law. Buyer and user assume all risk of use and handling of this material when such use and handling are contrary to the label directions. To the extent consistent with applicable law, any damages arising from a breach of Seller's warranties shall be limited to direct damages and shall not include consequential damages, such as loss of profits or diminution in value.

ALTERNATE MARKETING TEXT

{For use on front, side, or back panels of outer box or package insert}

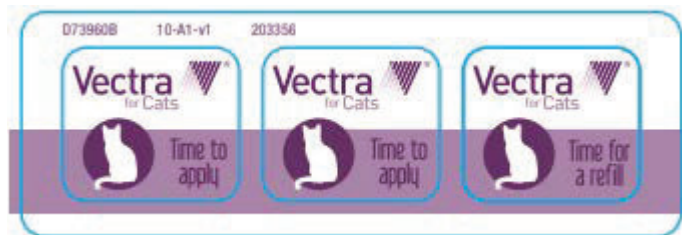
- Protects cats and kittens [under 9lbs and 8 weeks of age or older] {0.8 ml dose} from fleas, flea eggs, flea larvae and flea pupae (for one month)
- Protects cats (over 9 lbs and 8 weeks of age or older) {1.2ml dose} from fleas, flea eggs, flea larvae and flea pupae (for one month)
- For cats and kittens (weighing) 2 to 9 lbs and(over) 8 weeks of age (or older) {0.8 ml size only}
- For cats [weighing] 9 lbs and over {1.2 ml size only}
- [1] [2] [3] [4] [6] [8] [9] [12] [18] [24] [36] [single] dose[s] [applicators]
- Effective monthly treatment of [against] fleas, flea eggs, larvae and pupae on cats [and kittens]
- Protects [your cat and kitten] from all stages of fleas for one month
- Prevents development of fleas, flea eggs, flea larvae and [flea] pupae on cats
- Protects cats from fleas for one month
- Kills newly emerged fleas on cats before they lay eggs
- Kills fleas within 6 hours on cats
- Formulated for cats over 9 lbs {1.2 ml}
- Flea treatment formulated for cats over 9 lbs {1.2 ml dose}
- Flea treatment formulated for cats and kittens 2 to 9 lbs. {0.8ml dose}
- Easy, spot-on [topical] application
- [Patented] applicator tip [Trademark] for easy application directly to the skin

- Satisfaction guaranteed or your money back [Ceva ICON]. [Please] Call our professional staff at 1-800-999-0297 or e-mail us at contact.us@ceva.com if you have any questions or comments about SVP8].
- Satisfaction guaranteed [or] will provide new product [or your money back]
- Kills fleas on cats that may cause flea allergy dermatitis (FAD)
- Complete flea control [for cat and kittens]
- SVP8 contains the insecticide dinotefuran, a neonicotinoid with knockdown effect. Pyriproxyfen is an insect growth regulator which controls development of immature fleas.
- SVP8 contains the insecticide dinotefuran, a neonicotinoid with knockdown effect and pyriproxyfen, an insect growth regulator which controls development of immature fleas.
- Satisfaction guaranteed or Ceva Animal Health, LLC will supply replacement product (or your money back)
- Persistent efficacy through 30 days
- Prevents [re-]infestation of fleas for one month
- Monthly treatment [all year] is recommended for optimal control and prevention of fleas
- Once monthly application
- X applicators [doses]
- X monthly doses [applications] [treatments]
- Quick drying, [and] non-greasy
- Easy to apply spot-on applicator
- Easy to apply spot-on [patented] applicator tip allows the product to be applied directly to the skin
- Convenient, easy to apply
- Fragrance [odor] free
- No noticeable [lingering] odors
- Convenient to use
- Convenient [easy to apply] topical treatment
- Still works after exposure to sunlight
- Convenient [easy to apply] topical treatment [with (patented) applicator tip] [that allows application down to the skin]
- Formulated for cats [and kittens]
- Available from [licensed] veterinarians
- Sold by veterinarians
- SVP8 provides ongoing protection against fleas [and the diseases they may transmit] for one month
- Effective monthly control of multiple flea stages on cats
- After application, SVP8 spreads over the cat's body to provide [full body] [all-over] protection against all stages of fleas
- SVP8 contains dinotefuran, a neonicotinoid insecticide, which is specific to the nervous system of insects.
- SVP8 contains dinotefuran, a neonicotinoid insecticide, specific to the acetylcholine receptors of the insect nervous system

- Dinotefuran kills fleas within 6 hours on cats
- SVP8 kills fleas within 6 hours on cats
- Questions or comments—please call (tel. no.) or e-mail us at contact.us@ceva.com
- For more information call (tel. no.)
- SVP8 protects cats [and kittens] from fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*
- SVP8 protects cats [and kittens] from fleas that may carry and transmit *Francisella tularensis*
- SVP8 kills fleas that may carry and transmit *Rickettsia felis*, *Rickettsia typhi* and *Francisella tularensis*
- For emergencies call (tel. no.)
- Kills fleas that may transmit disease, including bartonellosis , tapeworm and tularemia
- Controls fleas [all stages of fleas]
- Easy to apply, effective control of fleas that lasts 1 month [30 days] [4 weeks]
- Kills fleas within 6 hours
- Kills fleas that may transmit disease, such as bartonellosis and tapeworm disease
- Regular use breaks the flea life cycle
- Starts working with first application and continues to kill all fleas and immature fleas for up to one month
- Starts with first application, killing fleas in 6 hours
- Recommended for use in an integrated flea management system
- Treating cats (and kittens under 9lbs and over 8 weeks of age) with SVP8 kills fleas that may cause flea allergy dermatitis (FAD)
- Kills fleas that may cause flea allergy dermatitis (FAD) and anemia
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treating cats with SVP8 kills fleas and may reduce the incidence of FAD.
- SVP8 is useful for cats (and kittens) susceptible to Flea Allergy Dermatitis (FAD)
- SVP8 contains the insect growth regulator pyriproxyfen that acts to prevent the development of all immature fleas for one month (30 days) (4 weeks)
- Regular use (of SVP8) protects your cat (and kitten) against all stages of the flea life cycle
- Proven formulation for [problem] flea infestations
- Pyriproxyfen has an anti-feeding effect on adult fleas, thereby preventing the flea from taking a blood meal
- Pyriproxyfen [the insect growth regulator] found in SVP8 stops the development of immature fleas
- Pyriproxyfen controls immature fleas
- A single dose effectively stops flea infestation and prevents re-infestation for one month [30 days, 4 weeks]
- For both indoor and outdoor cats [and kittens]
- Single spot control for all flea stages
- SVP8 may be used to prevent flea infestation on flea-free cats [and kittens]

- SVP8 prevents infestation on flea-free cats [and kittens] and protects animals in flea infested environments
- Kills adult fleas on cats [and kittens] which may cause flea allergy dermatitis (FAD)
- SVP8, flea control for an age old problem
- Patented applicator tip makes it easier to apply and minimizes risk of skin abrasion
- Controls and stops flea infestations
- Prevents [flea] re-infestation
- Kitten pack [24 and 36 applicator packs, {0.8 ml size only}]
- Feline (cat) pack [24 and 36 applicator packs, {1.2ml size only}]
- Kills fleas and prevents infestation for one month
- Apply monthly for long lasting flea control and year round protection
- SVP8 kills more than the adult fleas you see, it controls immature fleas on cats [and kittens]
- Fleas do not have to bite to die
- SVP8 kills fleas through contact
- SVP8 kills not only adult fleas, it breaks the flea life cycle [flea life cycle diagram]
- Kills existing flea infestations on your cat [kitten]
- Kills adult fleas and controls immature fleas with two effective ingredients (dinotefuran and pyriproxyfen)
- Proven effective topical flea control for cats [and kittens] containing dinotefuran and pyriproxyfen
- SVP8 contains [pyriproxyfen] a photostable insect growth regulator (IGR) [for control of all immature flea stages]
- After application, SVP8 spreads over the cat's body to provide [full body] all-over protection against all flea stages
- Remains effective after exposure to sunlight
- Kills fleas so they can't lay eggs
- Contains pyriproxyfen an insect growth regulator
- Kills fleas on cats [and] [kittens] that may cause anemia
- Protect your cat from flea infestation that may cause anemia
- Pyriproxyfen provides ovicidal activity
- Available from [Ceva authorized] [Seller authorized] [approved] [endorsed] [certified] [qualified] veterinarians.
- Available from licensed veterinarians. Ceva [Company name] reserves the right to take appropriate [legal] action if this product is sold by an unauthorized person.
- Available wherever Ceva [authorized] products are sold.

NEXT DOSE STICKERS



APPLICATOR LABELING

SVP8 for Cats

Alternate Brand Names:

[Vectra for Cats] [Vectra Plus for Cats] [Vectra Excel for Cats] [Vectra Dual for Cats] [Vectra 2C for Cats] [Vectra Duo for Cats] [Vectra II for Cats] [Vectra 2 for Cats] [Vectra Gold for Cats] [Vectra Shield for Cats] [SimpleGuard for Cats]
Over 9 lbs {1.2ml dose}

[Vectra for Cats and Kittens] [Vectra Plus for Cats and Kittens] [Vectra Excel for Cats & Kittens] [Vectra Dual for Cats & Kittens] [Vectra 2C for Cats & Kittens] [Vectra Duo for Cats & Kittens] [Vectra II for Cats & Kittens] [Vectra 2 for Cats & Kittens] [Vectra Gold for Cats & Kittens] [Vectra Shield for Cats and Kittens] [SimpleGuard for Cats & Kittens]
2 to 9 lbs[,] [and] over 8 weeks of age {0.8ml dose}

Dinotefuran.....22.00%
Pyriproxyfen.....3.00%

KEEP OUT OF REACH OF CHILDREN
WARNING

READ ENTIRE LABEL BEFORE USE

Use only on cats over [>] 8 weeks [of age], weighing [2 to 9 lbs] [over 9 lbs]

0.027 fl. oz. [(0.80 mL)]
0.041 fl. oz. [(1.20 mL)]

EPA Reg. No. 83399-9
EPA Est. No. TBD
Lot # {*designation will identify producing establishment*}

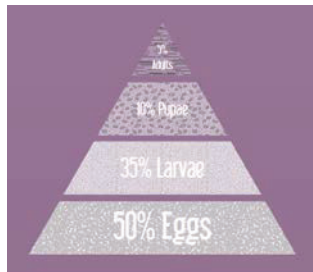
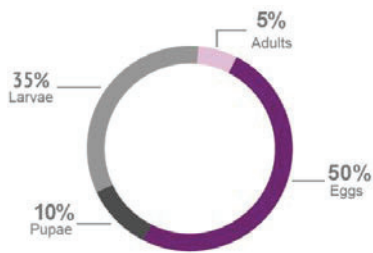
EXAMPLE PICTURES / PICTOGRAMS



Example applicator tube



Example pictograms of flea and flea larvae



Examples of flea life cycle diagrams