

COMBOGUARD™

(spinosad + milbemycin oxime)

Chewable Tablets

Your veterinarian has chosen to prescribe COMBOGUARD Chewable Tablets for the prevention of heartworm disease (*Dirofilaria immitis*), to kill fleas and for the prevention and treatment of flea infestations (*Ctenocephalides felis*), and the treatment and control of adult hookworm (*Ancylostoma caninum*), adult roundworm (*Toxocara canis* and *Toxascaris leonina*) and adult whipworm (*Trichuris vulpis*) infections in dogs and puppies 8 weeks of age or older and 5 pounds of body weight or greater. Controlling these parasites is very important to the health of your dog. Please read this leaflet, which describes the proper use of COMBOGUARD. If you have any questions about this information, please consult your veterinarian. Additional information can be found at www.vethical.com.

What is COMBOGUARD?

COMBOGUARD is a chewable, flavored tablet that you give orally to your dog once-a-month to kill fleas, to prevent flea infestations, to treat and control hookworms, whipworms and roundworms, and to prevent heartworm disease. COMBOGUARD is for monthly use in dogs and puppies 8 weeks of age or older and 5 pounds of body weight or greater. If you do not administer COMBOGUARD monthly throughout the year, the final dose must be given no fewer than three months following the last exposure to mosquitoes.

Why has my veterinarian prescribed COMBOGUARD?

Your veterinarian has prescribed COMBOGUARD as a way of preventing your dog from developing problems caused by infection with three commonly occurring parasite categories. **Heartworm infection** can make dogs very sick and can even be fatal. This parasite is spread to dogs by mosquitoes. COMBOGUARD can prevent **flea infestations** from becoming established, and can also remove any fleas that are on your dog at the time of treatment. COMBOGUARD will also treat and control common adult **intestinal worm infections** (roundworms, hookworms and whipworms).

Should I give COMBOGUARD each month all year round?

Consult your veterinarian regarding the need for year round use of COMBOGUARD. If you do not administer COMBOGUARD monthly throughout the year, the final dose must be given no fewer than three months following the last exposure to mosquitoes.

Will COMBOGUARD kill heartworms?

COMBOGUARD prevents heartworm disease by killing certain stages that develop after an infected mosquito bites a dog. As with other heartworm preventatives, COMBOGUARD does not kill adult heartworms. Speak to your veterinarian about treatment options if your dog is diagnosed with an adult heartworm infection.

Will my dog still need to be tested for heartworm infection while taking COMBOGUARD?

You should speak to your veterinarian about the frequency of heartworm testing while your dog is taking COMBOGUARD.

How do I switch to COMBOGUARD from another heartworm preventative?

Follow the advice of your veterinarian about switching heartworm preventatives.

What should I discuss with my veterinarian regarding COMBOGUARD for my dog?

Your veterinarian is your dog's healthcare expert and can make the best recommendation for medications for your dog. This includes the prevention, control and/or treatment of parasites such as fleas, heartworms and intestinal parasites that may cause conditions that include flea allergy dermatitis, anemia and heart disease. Key points of your discussion may include the following:

- As with other heartworm preventatives, dogs should be tested for heartworm prior to beginning treatment with COMBOGUARD.
- If a dose is missed and a monthly interval between doses is exceeded, then immediately give COMBOGUARD with food and resume monthly dosing. This practice will minimize the opportunity for heartworms to grow. Also, continuing normal monthly dosing will allow you to gain control of any flea or intestinal parasites that might have infected your dog.
- To minimize the likelihood of fleas continuing to jump onto your dog, it is important to treat all household pets with an approved flea protection product.
- COMBOGUARD is not for use in humans. Like all medications, keep COMBOGUARD out of reach of children.

How should I give COMBOGUARD to my dog?

Give COMBOGUARD with food for maximum effectiveness. COMBOGUARD is a chewable tablet and may be offered as a treat. Consult your veterinarian regarding the need for year round administration of COMBOGUARD. To help you remember the monthly dosing schedule, stick-on labels are included for your calendar.

What if I give more than the prescribed amount of COMBOGUARD to my dog?

Contact your veterinarian as soon as possible if you believe your dog has ingested more than the recommended dose of COMBOGUARD. In a study in which dogs were dosed at 1, 3, and 5 times the upper half of the recommended dose, dogs exhibited vomiting, tremors, decreased activity, salivation, coughing and vocalization.

Should I restrict either my dog's activity or contact with my dog after the tablet is consumed?

Since COMBOGUARD is an oral formulation, you may maintain normal activities and interactions with your dog.

How quickly will COMBOGUARD kill fleas?

In a laboratory study of spinosad alone, an active ingredient of COMBOGUARD, spinosad started to kill fleas within 30 minutes and killed 100% of the fleas within 4 hours. COMBOGUARD kills fleas before they can lay eggs.

Does seeing fleas on my dog mean that the treatment is not working?

COMBOGUARD kills fleas before they can lay eggs when used monthly according to the label directions. Remember that all animals in the household should be treated with an approved flea product to help control the flea population.

Your dog can continue to be exposed to the fleas that live in the environment. When fleas jump onto your dog, they will be killed by COMBOGUARD.

If within a month after your dog receives COMBOGUARD you see fleas on your dog, it is most likely that these are new fleas. These new fleas will be killed before they can produce eggs that contaminate the environment. Continued monthly use of COMBOGUARD can prevent any new infestations.

What if I see worms in my dog's stool during the month after administration of COMBOGUARD?

COMBOGUARD is indicated to treat and control intestinal parasite infections of adult hookworms, roundworms and whipworms. In occasional cases, it is possible that the action of COMBOGUARD in killing the intestinal worms will lead to the dog expelling them in the stool. If you have questions, consult with your veterinarian for measures you can take to prevent a reinfection with intestinal parasites.

Is it safe to give my dog COMBOGUARD?

COMBOGUARD has been demonstrated to be safe in pure and mixed breeds of healthy dogs when used according to label directions for dogs and puppies 8 weeks of age and older and five pounds of body weight or greater. You should discuss the use of COMBOGUARD with your veterinarian prior to use if your dog has a history of epilepsy (seizures). Puppies less than 14 weeks of age may experience a higher rate of vomiting.

Is it safe to give my breeding dogs COMBOGUARD?

Ask your veterinarian about the use of COMBOGUARD prior to use in breeding females. The safe use of COMBOGUARD in male dogs intended for breeding has not been evaluated.

What side effects might occur with COMBOGUARD?

Like all medications, sometimes side effects may occur. In some cases, dogs vomited after receiving COMBOGUARD. To ensure heartworm prevention, observe your dog for one hour after administration. If vomiting occurs within an hour of administration, redose with another full dose. During field studies, no severe or prolonged vomiting occurred. Additional adverse reactions observed in the clinical studies were itching, decreased activity, diarrhea, inflammation of the skin, redness of the skin, decreased appetite and redness of the ear. All reactions were regarded as mild.

Since the introduction of COMBOGUARD, additional side effects reported are trembling/shaking, ataxia, seizures and hypersalivation. For technical assistance or to report a suspected adverse drug reaction, call 1-888-545-5973. Additional information can be found at www.vethical.com. Alternatively, suspected adverse drug reactions may be reported to FDA at 1-888-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm>

Can other medications be given while my dog is taking COMBOGUARD?

Yes, COMBOGUARD has been given safely with a wide variety of products and medications. Your veterinarian should be made aware of all products that you administered and/or intend to administer to your dog.

How should COMBOGUARD be stored?

Store at 68-77°F (20-25°C). Temporary periods of time outside this range between 59-86°F (15 -30°C) are permitted.

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