

# Protect your dog from dangerous parasites.

When it comes to fleas, ticks, heartworm and other pests, there's no such thing as a risk-free dog.

## Choose tailored protection based on how and where your dog lives.



### There's no such thing as a risk-free dog.

Dogs that love the outdoors are at highest risk of exposure to infected biting pests. But even dogs who spend most of their time indoors face risks from open doors, windows, other pets, and even you can bring dangerous pests into your home.

Protect your dog with monthly topical protection to fight biting pests and kill them through contact, no bite required. Minimize the risk of infected pests spreading disease and illness. Pair with a monthly heartworm preventive and de-wormer to provide full protection. Dogs should be tested for heartworm and treated, if positive, before using MilbeGuard®.

TALK TO YOUR VET TODAY ABOUT THE BEST TAILORED PROTECTION FOR YOUR DOG'S LIFESTYLE.

FROM THE MAKERS OF









INFORMATION FOR DOSING DOGS

The once-a-month tablet that prevents heartworm disease, controls adult hookworm, and removes and controls adult roundworm and whipworm infections in doos and puppies.

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Keep this and all drugs out of the reach of children.

Description: MILBEGUARD® (millbemycin oxime) Flavored Tablets are available in four tablet sizes in color-coded packages for oral administration to dogs and puppies. Each tablet is formulated to provide a minimum of 0.23 mg/lb (0.5 mg/kg) body weight of milbemycin oxime. Milbemycin oxime consists of the oxime derivatives of 5-didehydromilbemycins in the ratio of approximately 80% A4 (CaHesNO<sub>7</sub>, MW 555.71) and 20% A3 (CaHesNO<sub>7</sub>, MW 541.68).

Package color	Milbemycin oxime tablet
Yellow	2.3 mg*
Blue	5.75 mg
Purple	11.5 mg
Red	23.0 mg

<sup>\*</sup>for dogs only

Indications: MILBEGUARD® Flavored Tablets are indicated for use in the prevention of heartworm disease caused by Dirofilaria immitis, the control of adult Ancylostoma caninum (hookworm), and the removal and control of adult Toxocara canis and Toxascaris Jeonina (roundworms) and Trichuris vulpis (whipworm) infections in dogs and in puppies four weeks of age or greater and two pounds body weight or greater.

**Dosage:** MILBEGUARD® Flavored Tablets are given orally, once a month, at the recommended minimum dosage rate of 0.23 mg milbemycin oxime per pound of body weight (0.5 mg/kg).

#### Recommended Dosage Schedule for Dogs

MilbeGuard® Flavored Tablets
One tablet (2.3 mg)
One tablet (5.75 mg)
One tablet (11.5 mg)
One tablet (23.0 mg)

Dogs over 100 lbs. are provided the appropriate combination of tablets.

**Administration:** MILBEGUARD® Flavored Tablets are dual-purpose and may be offered in food or administered as other tablet medications. Watch the dog closely following dosing to be sure the entire dose has been consumed. If it is not entirely consumed, redose once with the full recommended dose as soon as possible.

MILBEGUARD® Flavored Tablets must be administered monthly, preferably on the same date each month. The first dose should be administered within one month of the dog's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. If a dose is missed and a 30-day interval between dosing is exceeded, administer MILBEGUARD® Flavored Tablets immediately and resume the monthly dosing schedule.

If MILBEGUARD® Flavored Tablets replaces diethylcarbamazine (DEC) for heartworm prevention, the first dose must be given within 30 days after the last dose of DEC.

Precautions: Do not use in puppies less than four weeks of age or less than two pounds of body weight. Prior to initiation of the MILBEGUARD\* Flavored Tablets treatment program, dogs should be tested for existing heartworm infections. Infected dogs should be treated to remove adult heartworms and microfilariae prior to initiating treatment with MILBEGUARD\* Flavored Tablets. Mild, transient hypersensitivity reactions manifested as labored respiration, vomiting, salivation and lethargy, have been noted in some treated dogs carrying a high number of circulating microfilariae. These reactions are presumably caused by release of protein from dead or dying microfilariae.

Adverse Reactions: The following adverse reactions have been reported following the use of MILBEGUARD® Flavored Tablets: Depression/lethargy, vomiting, ataxia, anorexia, diarrhea, convulsions, weakness and hypersalivation.

Efficacy: MILBEGUARD® Flavored Tablets eliminate the tissue stage of heartworm larvae and the adult stage of hookworm (Ancylostoma caninum), roundworms (Toxocara canis, Toxoscaris leonina) and whipworm (Trichuris vulpis) infestations when administered orally according to the recommended dosage schedule. The anthelmintic activity of milbemycin oxime is believed to be a result of interference with invertebrate neurotransmission.

Safety: Milbemycin oxime has been tested safely in over 75 different breeds of dogs, including collies, pregnant females, breeding males and females, and puppies over two weeks of age. In well-controlled clinical field studies, 786 dogs completed treatment with milbemycin oxime. Milbemycin oxime was used safely in animals receiving frequently used veterinary products such as vaccines, anthelmintics, antibiotics, steroids, flea collars, shampoos and dips.

Two studies in heartworm-infected dogs were conducted which demonstrated mild, transient hypersensitivity reactions in treated dogs with high microfilaremia counts (see Precautions for reactions observed). Safety studies in pregnant dogs demonstrated that high doses (1.5 mg/kg = 3X) of milbernycin oxime given in an exaggerated dosing regimen (daily from mating through weaning), resulted in measurable concentrations of the drug in milk. Puppies nursing these females which received exaggerated dosing regimens demonstrated milbernycin-related effects. These effects were directly attributable to the exaggerated experimental dosing regimen. The product is normally intended for once-a-month administration only. Subsequent studies included using 3X daily from mating to one week before weaning and demonstrated no effects on the pregnant females or their litters. A second study where pregnant females were dosed once at 3X the monthly use rate either before, on the day of or shortly after whelping resulted in no effects on the puppies.

Some nursing puppies, at 2, 4, and 6 weeks of age, given greatly exaggerated oral milbemycin oxime doses (9.6 mg/kg = 19X) exhibited signs typified by tremors, vocalization and ataxia. These effects were all transient and puppies returned to normal within 24 to 48 hours. No effects were observed in puppies given the recommended dose of milbemycin oxime (0.5 mg/kg). This product has not been tested in doos less than 1 kg weight.

A rising-dose safety study conducted in rough-coated collies, manifested a clinical reaction consisting of ataxia, pyrexia and periodic recumbency, in one of fourteen dogs treated with milbernycin oxime at 12.5 mg/kg (25X monthly use rate). Prior to receiving the 12.5 mg/kg dose (25X monthly use rate) on day 56 of the study, all animals had undergone an exaggerated dosing regimen consisting of 2.5 mg/kg milbernycin oxime (5X monthly use rate) on day 0, followed by 5.0 mg/kg (10X monthly use rate) on day 14 and 10.0 mg/kg (20X monthly use rate) on day 32. No adverse reactions were observed in any of the collies treated with this regimen up through the 10.0 mg/kg (20X monthly use rate) dose.

**How supplied:** MILBEGUARD® Flavored Tablets are available in four tablet sizes (see Dosage section), formulated according to the weight of the dog. Each tablet size is available in color-coded packages of 6 tablets each, which are packaged 10 per display carton.

 $\textbf{Storage conditions:} \ \textbf{MILBEGUARD} \\ \textbf{§ Flavored Tablets should be stored at room temperature, between 68} \\ \textbf{and 77} \\ \textbf{§ (20-25°C)}. \\ \textbf{(20-25°C)}. \\ \textbf{(20-25°C)}$ 

Keep MILBEGUARD® (milbemycin oxime) Flavored Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

#### Manufactured for:

Ceva Animal Health, LLC Lenexa, KS 66215

Made in Canada.

Approved by FDA under ANADA # 200-629



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