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INTERCEPTOR® FLAVOR TABS® FOR DOGS & CATS



Novartis

(milbemycin oxime)

INFORMATION FOR DOSING DOGS

The palatable once-a-month tablet that prevents heartworm disease, controls adult hookworm, and removes and controls adult roundworm and whipworm infections in dogs 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: INTERCEPTOR (milbemycin oxime) Flavor Tabs 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 (C₃₂H₄₅NO₇, MW 555.71) and 20% A₃ (C₃₁H₄₃NO₇, MW 541.68).

Package color	Milbemycin oxime tablet
Brown	2.3 mg*
Green	5.75 mg
Yellow	11.5 mg
White	23.0 mg

*for dogs only

Indications: INTERCEPTOR Flavor Tabs 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 leonina* (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: INTERCEPTOR Flavor Tabs 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

Body Weight	INTERCEPTOR Flavor Tabs
2-10 lbs.	One tablet (2.3 mg)
11-25 lbs.	One tablet (5.75 mg)
26-50 lbs.	One tablet (11.5 mg)
51-100 lbs.	One tablet (23.0 mg)

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

Administration: INTERCEPTOR Flavor Tabs are palatable and most dogs will consume the tablet willingly when offered by the owner. As an alternative, the dual-purpose tablet 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.

INTERCEPTOR Flavor Tabs 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 INTERCEPTOR Flavor Tabs immediately and resume the monthly dosing schedule.

If INTERCEPTOR Flavor Tabs replaces diethylcarbamazine (DEC) for heartworm prevention, the first dose must be given within 30 days after the last dose of DEC.

Palatability: Palatability trials conducted in 244 dogs from 10 different U.S. veterinary practices demonstrated that INTERCEPTOR Flavor Tabs were willingly accepted from the owner by over 95% of dogs. The trial was comprised of dogs representing 60 different breeds and both sexes, with weights ranging from 2.1 lbs. to 143.3 lbs., and ages ranging from 8 weeks to 15 years.

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 INTERCEPTOR Flavor Tabs 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 INTERCEPTOR Flavor Tabs. 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 INTERCEPTOR Flavor Tabs: Depression/lethargy, vomiting, ataxia, anorexia, diarrhea, convulsions, weakness and hypersalivation.

Efficacy: INTERCEPTOR Flavor Tabs eliminate the tissue stage of heartworm larvae and the adult stage of hookworm (*Ancylostoma caninum*), roundworms (*Toxocara canis*, *Toxascaris 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 milbemycin 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 milbemycin-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 dogs 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 milbemycin 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 milbemycin 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: INTERCEPTOR Flavor Tabs 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 or 12 tablets each, which are packaged 10 per display carton.

Storage conditions: INTERCEPTOR Flavor Tabs should be stored at room temperature, between 59° and 77°F (15-25°C).

INFORMATION FOR DOSING CATS

The palatable once-a-month tablet that prevents heartworm disease and removes adult roundworms and hookworms in cats and kittens.

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: INTERCEPTOR Flavor Tabs for Cats are available in three tablet sizes in color-coded packages for oral administration to cats and kittens. Each tablet is formulated to provide a minimum of 0.9 mg/lb (2.0 mg/kg) body weight of milbemycin oxime. Milbemycin oxime consists of the oxime derivatives of 5-

didehydromilbemycins in the ratio of approximately 80% A₄ (C₃₂H₄₅NO₇, MW 555.71) and 20% A₃ (C₃₁H₄₃NO₇, MW 541.68).

Indications: INTERCEPTOR Flavor Tabs for Cats are indicated for use in the prevention of heartworm disease caused by *Dirofilaria immitis*, and the removal of adult *Ancylostoma tubaeforme* (hookworm) and *Toxocara cati* (roundworm) in cats and kittens six weeks of age or greater and 1.5 lbs. body weight or greater.

Dosage: INTERCEPTOR Flavor Tabs for Cats are given orally, once a month, at the recommended minimum dosage rate of 0.9 mg milbemycin oxime per pound of body weight (2.0 mg/kg).

Recommended Dosage Schedule for Cats

Body Weight	INTERCEPTOR Flavor Tab
1.5 to 6 lbs.	One tablet (5.75 mg)
6.1-12 lbs.	One tablet (11.5 mg)
12.1-25 lbs.	One tablet (23.0 mg)

Cats over 25 lbs. are provided the appropriate combination of tablets.

Administration: INTERCEPTOR Flavor Tabs for Cats are palatable and may be offered by the owner as a treat. As an alternative, the tablet may be offered in food or administered as other tablet medications. The tablets can be broken for ease of administration. Watch the cat 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.

INTERCEPTOR Flavor Tabs for Cats must be administered monthly, preferably on the same date each month. The first dose should be administered within one month of the cat'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 INTERCEPTOR Flavor Tabs for Cats immediately and resume the monthly dosing schedule. It is recommended that cats be tested for existing heartworm infection prior to starting treatment with Flavor Tabs for Cats (see Precautions).

Palatability: Palatability trials conducted in 72 cats demonstrated that INTERCEPTOR Flavor Tabs for Cats were successfully dosed by the owner when they either offered the tablet as a treat, placed the tablet in the cat's mouth or placed the tablet in the cat's food in 72% of cats. About 16% of the cats were manually dosed and 13% of the cats were not successfully dosed according to the protocol.

Precautions: Do not use in kittens less than six weeks of age or less than 1.5 lbs. body weight. Safety in heartworm-positive cats has not been established. Safety in breeding, pregnant, and lactating queens and breeding toms has not been established.

Efficacy: INTERCEPTOR Flavor Tabs for Cats eliminate the tissue stage of heartworm larvae and hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections 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 8 different breeds of cats. In well-controlled clinical field studies 141 cats completed treatment with milbemycin oxime. Milbemycin oxime was used safely in animals receiving frequently used veterinary products such as vaccines, anthelmintics, anesthetics, antibiotics, steroids, flea collars, shampoos and dips.

Safety studies were conducted in young cats and kittens and doses of 1X, 3X and 5X the minimum recommended dose of 2.0 mg/kg demonstrated no drug-related effects. Tolerability studies at exaggerated doses of 10X also demonstrated no drug-related adverse effects in kittens and young adult cats.

How supplied: INTERCEPTOR Flavor Tabs for Cats are available in three tablet sizes (see Dosage section), formulated according to the weight of the cat. Each tablet size is available in color-coded packages of 6 or 12 tablets each, which are packaged 10 per display carton.

Storage conditions: INTERCEPTOR Flavor Tabs for Cats should be stored at room temperature, between 59° and 77°F (15-25°C).

Manufactured for: Novartis Animal Health US, Inc., Greensboro, NC 27408, USA

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