



Flavor Tabs™ (milbemycin oxime)

DOGS

Indications

INTERCEPTOR® Flavor Tabs™ are recommended for the **prevention of heartworm disease** caused by *Dirofilaria immitis* and for the **treatment and control of parasitic infections due to adult hookworm** (*Ancylostoma caninum*), **adult roundworms** (*Toxocara canis* and *Toxascaris leonina*), and **adult whipworm** (*Trichuris vulpis*) in dogs two weeks of age or greater.

Dosage

Available in four sizes for convenient dosing of dogs of various weights.

Dog Weight	Package Colour	Active Ingredient/ Tablet	Tablet Imprint
Up to 4.5 kg	Brown	2.3 mg	CGV/RN
5 to 11 kg	Green	5.75 mg	CGV/GO
12 to 22 kg	Yellow	11.5 mg	CGV/FKF
23 to 45 kg	White	23 mg	CGV/FRF

The minimum dosage level is 0.5 mg/kg of body weight. Dogs weighing over 45 kg should receive the appropriate combination of Flavor Tabs.

For heartworm prevention, administer INTERCEPTOR Flavor Tabs **once per month** on the same day.

Reminder stickers are provided for use on a calendar.

The initial dose must be given within a month after the first indication of mosquito activity and regular dosing should continue until at least one month after the end of the mosquito season. If the interval between doses exceeds 30 days, the efficacy of INTERCEPTOR may be reduced. If regular monthly treatment is delayed, it is essential to immediately recommence treatment at the recommended dosage rate. If treatment has been delayed beyond two months, the advice of a veterinarian should be sought. When replacing an existing diethylcarbamazine citrate (DEC) or ivermectin based product, the initial dose of INTERCEPTOR may be given at any time within 30 days of the last treatment with that product.

For hookworm, roundworm and whipworm, control will be obtained in conjunction with heartworm prevention, or by separate administration of INTERCEPTOR Flavor Tabs. INTERCEPTOR should be given to puppies at 2, 4, 6, 8, 10 and 12 weeks of age, then monthly to 6 months of age. In non-heartworm endemic areas, adult dogs should be treated a minimum of 4 times per year, or as directed by the veterinarian.

Administration

INTERCEPTOR Flavor Tabs are highly palatable and may be given by hand. They may also be added to dog food or administered as a regular tablet.

The tablet(s) should be placed into the dog's mouth on the back of the tongue, or can be hidden in food. The dog should be watched closely for several minutes following administration of the INTERCEPTOR Flavor Tab to ensure that the entire dose has been swallowed. If it is suspected that any of the dose has been lost, dosing should be repeated.

Safety Studies

INTERCEPTOR has been tested and found to have no adverse reactions in over 75 dog breeds, pregnant females, breeding males and females, and puppies greater than 2 weeks of age and one (1) kilogram body weight when administered at the recommended monthly dosage.

Five **pivotal** target animal studies provided evidence that milbemycin oxime can be used safely in dogs. Milbemycin was administered daily to reproducing dogs, prior to mating and during gestation, without detectable adverse effects.

In a chronic study (10 months) milbemycin was given to dogs at rates up to 5X the monthly use rate, on three consecutive days. The only adverse effects found were transient ataxia and trembling in some 8-week old puppies. An additional study in 8-week old puppies demonstrated no adverse effects when milbemycin was given for 3 days at the proposed rate and only minor effects in a few animals at the 5X rate given daily for 3 days.

Two specifically designed target animal safety studies in puppies 2 weeks of age were conducted. These studies demonstrated a very adequate margin of safety for the use of milbemycin in young puppies between 2 and 8 weeks of age.

Seven **supportive** animal safety studies provided evidence that milbemycin oxime would not be expected to have adverse effects in dogs under normal use conditions and up to 3X the recommended use rate.

Caution

Prior to initiation of INTERCEPTOR Flavor Tab treatment for the first time, dogs 6 months of age or older should be tested for existing heartworm infections. Dogs on preventive medication should be retested at the start of the following season. Thereafter, testing is performed at the veterinarian's discretion. If positive, dogs should be converted to negative status by the use of appropriate heartworm adulticides prior to INTERCEPTOR use.

When milbemycin was administered to heartworm-infected dogs, a relatively mild shock-like reaction was observed, probably due to the microfilaricidal effect of milbemycin.

Warning

Keep out of reach of children. If accidentally swallowed, call a physician.

Presentation

INTERCEPTOR is available in four Flavor Tab sizes, formulated and package colour coded according to the weight range of the dog.

Available in the following package size: 6 INTERCEPTOR Flavor Tabs packaged 10 per display carton.

CATS

Indications

INTERCEPTOR Flavor Tabs are recommended for the **prevention of heartworm disease** caused by *Dirofilaria immitis* and for the **treatment and control of parasitic infections due to adult hookworm** (*Ancylostoma tubaeform*) and **adult roundworm** (*Toxocara cati*) in cats two weeks of age or greater.

Dosage

Available in four sizes for convenient dosing of cats of various weights.

Cat Weight	Package Colour	Active Ingredient/ Tablet	Tablet Imprint
Up to 1.1 kg	Brown	2.3 mg	CGV/RN
1.2 to 2.8 kg	Green	5.75 mg	CGV/GO
2.9 to 5.7 kg	Yellow	11.5 mg	CGV/FKF
5.8 to 11.5 kg	White	23.0 mg	CGV/FRF

The minimum dosage level is 2 mg/kg of body weight. Cats weighing over 11.5 kg should receive the appropriate combination of INTERCEPTOR Flavor Tabs.

For heartworm prevention, administer INTERCEPTOR Flavor Tabs **once per month** on the same day.

Reminder stickers are provided for use on a calendar.

The initial dose must be given within a month after the first indication of mosquito activity and regular dosing should continue until at least one month after the end of the mosquito season. If the interval between doses exceeds 30 days, the efficacy of INTERCEPTOR may be reduced. If regular monthly treatment is delayed, it is essential to immediately recommence treatment at the recommended dosage rate. If treatment has been delayed beyond two months, the advice of a veterinarian should be sought.

For hookworm and roundworm, control will be obtained in conjunction with heartworm prevention, or by separate administration of INTERCEPTOR Flavor Tabs. Kittens should be treated every 2 weeks from 3 weeks of age to 3 months of age, then monthly until 6 months of age. In non-heartworm endemic areas, adult cats should be treated a minimum of 4 times per year, or as directed by the veterinarian.

Administration

INTERCEPTOR Flavor Tabs are highly palatable and may be given by hand. They may also be added to cat food or administered as a regular tablet.

The tablet(s) should be placed into the cat's mouth on the back of the tongue, or can be hidden in food. The cat should be watched closely for several minutes following administration of the Flavor Tab to ensure that the entire dose has been swallowed. If it is suspected that any of the dose has been lost, dosing should be repeated.

Safety Studies

INTERCEPTOR Flavor Tabs (milbemycin oxime) has been tested safely in over 8 different breeds of cats and kittens, two weeks of age or greater. In clinical field studies, 310 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 beginning at two weeks of age. Doses of 1X, 3X and 5X 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.

Heartworm Disease in Cats

Much of the damage due to heartworm disease in cats occurs before there are any outward signs of the disease, and these signs may be quite variable. Prevention of the disease is important.

The disease is caused by *Dirofilaria immitis* which lives in the right side of the heart and adjacent blood vessels. A cat not on preventive medication can be infected with several worms. The adult worms cause disease by damaging blood vessels in the lungs which obstructs normal blood flow. This can result in an increased workload on the heart which can cause heart failure. The adult worms can also migrate into other tissues of the central nervous system such as the brain.

The disease is spread from animal to animal by any one of over 70 species of mosquitoes. Female adult heartworms discharge larval forms (microfilariae) into the bloodstream of a cat. The mosquito becomes infected by sucking up these microfilariae as it takes a blood meal from an infected cat; during the next two to three weeks these microfilariae grow and molt twice inside the mosquito to reach the infective larval stage which enters another cat as the mosquito feeds again. In the cat, it takes about seven to eight months for these larvae to grow, move to the heart, mate and start the cycle again.

Caution

This product has not been tested in breeding cats, in pregnant queens or in heartworm positive cats.

Testing: Despite the fact that the sensitivity of the heartworm antigen tests is relatively low in cats, it is still considered good medical practice to test before administering chemoprophylaxis for the first time, if at least 8 months have passed since there was an opportunity for infection. The cat should be examined by a veterinarian prior to starting heartworm prevention medication.

Warning

Keep out of reach of children. If accidentally swallowed, call a physician.

Presentation

INTERCEPTOR is available in four Flavor Tab sizes, formulated and package colour coded according to the weight range of the cat.

Available in the following package size: 6 INTERCEPTOR Flavor Tabs packaged 10 per display carton.

Storage Conditions

INTERCEPTOR Flavor Tabs should be stored at room temperature, 15 - 30°C.

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