

Milbemax Tablets for Small Dogs and Puppies/Milbemax Tablets for Dogs

Introduction



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Presentation

MILBEMAX* Tablets for Small dogs and puppies: White, oblong tablets, scored on one side, containing 2.5 mg of Milbemycin oxime and 25 mg Praziquantel PhEur per tablet. One side bears the imprint ``AA'', the other side ``NA''.
MILBEMAX* Tablets for Dogs: White, round-shaped tablets containing 12.5 mg of Milbemycin oxime and 125 mg of Praziquantel PhEur per tablet. One side bears the imprint ``CCA'', the other side ``NA''.

Uses

MILBEMAX is a broad spectrum wormer indicated in the dog for the treatment of mixed infections by the adult cestodes **and** nematodes of the following species:

Cestodes: *Dipylidium caninum*, *Taenia spp.*, *Echinococcus spp.*, *Mesocestoides spp*

Nematodes: *Toxocara canis*, *Toxascaris leonina*, *Ancylostoma caninum*, *Trichuris vulpis*.

Crenosoma vulpis(reduction of the level of infection),

Angiostrongylus vasorum (reduction of the level of infection; see specific treatment schedule under dosage and administration).

Milbemax can also be used in the prevention of heartworm disease (*Dirofilaria immitis*), if concomitant treatment against cestodes is indicated. In this case the product should be administered monthly.

Dosage and administration

MILBEMAX tablets are administered at a minimum recommended dose rate of 0.5 mg milbemycin oxime and 5 mg praziquantel per kg body weight, given once orally.

MILBEMAX is given by oral administration with or after some food.

Depending on the bodyweight of the dog, the practical dosing is as follows:

Weight	MILBEMAX tablets for small dogs and puppies	MILBEMAX tablets for dogs
0.5 – 1 kg	½ tablet	
> 1 - 5 kg	1 tablet	
>5 – 10 kg	2 tablets	1 tablet
>10 – 25 kg		1 tablet
> 25 – 50 kg		2 tablets
> 50 – 75 kg		3 tablets

In cases where heartworm disease prevention is used and at the same time treatment against tapeworm is required, MILBEMAX can replace the monovalent product for the prevention of heartworm disease.

For *Angiostrongylus vasorum* infection, milbemycin oxime should be given four times at weekly intervals. It is recommended, where concomitant treatment against cestodes is indicated, to treat once with MILBEMAX and continue with the monovalent product containing milbemycin oxime alone, for the remaining three weekly treatments.

Contra-indications, warnings, etc

Do not use the 'tablets for Small dogs and Puppies' in dogs of less than 2 weeks of age and/or weighing less than 0.5 kg

Do not use the 'tablets for Dogs' in dogs weighing less than 5 kg.

The margin of safety in Collies and related breeds is less than in other dogs. In these dogs, the recommended dose should be strictly observed.

The tolerance of MILBEMAX in young puppies from these breeds has not been investigated.

Clinical signs in Collies are similar to those seen in the general dog population when overdosed.

The product can be toxic to fish and aquatic organisms and should not come into water courses.

Precautions for use

Treatment of dogs with a high number of circulating microfilariae can sometimes lead to the appearance of hypersensitivity reactions, such as pale mucous membranes, vomiting, trembling, laboured breathing or excessive salivation. These reactions are associated with the release of proteins from dead or dying microfilariae and are not a direct toxic effect of the product. The use in dogs suffering from microfilaremia is thus not recommended.

In heartworm risk-areas, or in the case it is known that a dog has been travelling to and from heartworm risk regions, before using MILBEMAX, a veterinary consultation is advised to exclude the presence of any concurrent infestation of *Dirofilaria immitis*. In the case of a positive diagnosis, adulticidal therapy is indicated before administering MILBEMAX.

Echinococcosis represents a hazard for humans. In case of Echinococcosis, specific guidelines on the treatment and follow up and on the safeguard of persons have to be followed. Experts or institutes of parasitology should be consulted. No studies have been performed with severely debilitated dogs or individuals with seriously compromised kidney or liver function. The product is not recommended for such animals or only according to a benefit/risk assessment by the responsible veterinarian.

In dogs less than 4 weeks old, tapeworm infection is unusual. Treatment of animals less than 4 weeks old with a combination product may therefore not be necessary.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

In case of overdosing, hyriasis, depression, drooling, paresis, trembling and/or staggered gait can occur in some dogs. The symptoms will disappear spontaneously within a day. No antidote is known

For animal treatment only.

Wash hands after use.

In the event of accidental ingestion of the tablets, particularly by a child, seek medical advice and show the doctor the pack and/or the leaflet.

Pregnancy and lactation

MILBEMAX can be used in breeding dogs including pregnant and lactating bitches.

Storage precautions

Do not store above 30°C.

Keep blister in the outer carton to protect from light.

In-use shelf life for half tablets is 1 month.

Keep out of the reach and sight of children.

Disposal

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

Legal category

POM-V

Packaging Quantities

Milbemax tablets for Small Dogs and Puppies: Box of 5 blisters with 10 tablets in each blister

Milbemax tablets for Dogs: Box of 5 blisters with 10 tablets in each blister

Further information

Milbemycin oxime belongs to the group of macrocyclic lactones and is active against mites, against larval and adult stages of nematodes as well as against larvae of *Dirofilaria immitis*.

The concurrent use of MILBEMAX with selamectin is well tolerated. No interactions were observed when the recommended dose of the macrocyclic lactone selamectin was administered during treatment with MILBEMAX at the recommended dose. In the absence of further studies, caution should be taken in the case of concurrent use of MILBEMAX and other macrocyclic lactones. Also, no such studies have been performed with reproducing animals.

Praziquantel is an acylated pyrazino-isoquinoline derivative active against cestodes and trematodes.

MILBEMAX is effective against *Dirofilaria immitis*, which is endemic in the USA and some parts of continental Europe. The product is also effective against *Echinococcus multilocularis* which is endemic in some parts of continental Europe and prophylactic treatment is required in all pets entering the UK under the PETS scheme or under quarantine conditions.

Marketing authorisation numbers

MILBEMAX tablets for Small Dogs
and Puppies Vm
12501/4132

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