Milbemax Tablets for small dogs and puppies/Milbemax Tablets for dogs

Introduction

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Presentation

MILBEMAX Tablets for Small dogs and puppies: Oblong shaped, white, with a score on both sides, containing 2.5mg of Milbemycin oxime and 25mg Praziquantel per tablet. One side bears the imprint "AA", the other side "NA".

MILBEMAX Tablets for Dogs: Round shaped, white, containing 12.5mg Milbemycin oxime and 125mg Praziquantel per tablet. One side bears the imprint "CCA", the other side "NA".

Uses

In dogs: treatment of mixed infections by 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).

The product can also be used in the prevention of heartworm disease (Dirofilaria immitis), if concomitant treatment against cestodes is indicated.

Dosage and administration

Minimum recommended dose rate: 0.5 mg milbemycin oxime and 5 mg praziquantel per kg are given orally as a single dose. The product should be administered with or after some food.

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

<table>
<thead>
<tr>
<th>Weight</th>
<th>MILBEMAX tablets for small dogs and puppies</th>
<th>MILBEMAX tablets for dogs</th>
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</thead>
<tbody>
<tr>
<td>0.5 – 1 kg</td>
<td>½ tablet</td>
<td>1 tablet</td>
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<tr>
<td>&gt; 1 - 5 kg</td>
<td>1 tablet</td>
<td>2 tablets</td>
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<tr>
<td>&gt;5 – 10 kg</td>
<td>2 tablets</td>
<td>1 tablet</td>
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<tr>
<td>&gt;5 – 25 kg</td>
<td>1 tablet</td>
<td>2 tablets</td>
</tr>
<tr>
<td>&gt;25 – 50 kg</td>
<td>2 tablets</td>
<td>3 tablets</td>
</tr>
<tr>
<td>&gt; 50 – 75 kg</td>
<td>3 tablets</td>
<td></td>
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</tbody>
</table>

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.

See also “Precautions for use”.

Studies with milbemycin oxime indicate that the margin of safety in certain dogs of Collie or related breeds is less than in other breeds. 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.

Precautions for use

As per good veterinary practice, animals should be weighed to ensure accurate dosing.

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 microfilaria 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 very rare occasions, systemic signs (such as lethargy), neurological signs (such as muscle tremors and ataxia) and/or gastrointestinal signs (such as emesis, diarrhoea, anorexia and drooling) have been observed in dogs after administration of the veterinary medicinal product. No other signs than those observed at the recommended dose have been observed.

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 package leaflet or the label to the doctor.

**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.

Keep out of the reach and sight of children.

**Disposal**

Any unused product or waste material should be disposed of in accordance with national requirements.

This product should not come into contact with water courses as this may be dangerous for fish and other aquatic organisms.

**Legal category**

POM-V

**Packaging Quantities**

Milbemax tablets for small dogs and puppies: Box of 5 blisters with 10 tablets in each blister AND box of 2 blisters with 2 tablets in each blister.

Milbemax tablets for dogs: Box of 5 blisters with 10 tablets in each blister AND box of 2 blisters with 2 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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