Virbac Limited

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Milpro film-coated tablets for Dogs and Puppies (GB Only)

Species: Dogs

Therapeutic indication:Pharmaceuticals: Endoparasiticides: Anthelmintics for dogs, Tapeworm products

Active ingredient: Milbemycin Oxime, Praziquantel

Product: Milpro Film-coated tablets for Dogs and Puppies

Product index: Milpro for Dogs and Puppies

Incorporating:

Qualitative and quantitative composition

Milpro for Small Dogs and Puppies:

Each tablet contains:

Active substances:

Milbemycin oxime 2.5 mg

Praziquantel 25 mg

Excipients:

Qualitative composition of excipients and other constituents

Core:

Microcrystalline cellulose

Croscarmellose sodium

Lactose monohydrate

Starch, pregelatinised

Povidone

Magnesium stearate

Silica hydrophobic colloidal

Coat:

Natural Poultry liver flavour

Hypromellose

Microcrystalline cellulose

Macrogol stearate

Oval shaped, beige to pale brown, meat flavoured tablets with a score on both sides. The tablets can be divided into halves.

Milpro for Dogs:

Each tablet contains:

Active substances:

Milbemycin oxime 12.5 mg

Praziquantel 125 mg

Excipients:

Qualitative composition of excipients and other constituents

Core:

Microcrystalline cellulose

Croscarmellose sodium

Lactose monohydrate

Starch, pregelatinised

Povidone

Magnesium stearate

Silica hydrophobic colloidal

Coat:

Natural Poultry liver flavour

Hypromellose

Microcrystalline cellulose

Macrogol stearate

Round shaped, beige to pale brown meat flavoured tablets.

Pharmaceutical form

Film-coated tablets.

Clinical particulars

Target species

DOGS

Indications for use

In dogs: treatment of mixed infections by adult cestodes (tapeworms) and nematodes (roundworms) of the following species:

Cestodes:

Dipylidium caninum,

Taenia spp.,

Echinococcus spp.,

Mesocestoides spp.

Nematodes:

Ancylostoma caninum,

Toxocara canis,

Toxascaris leonina,

Trichuris vulpis,

Thelazia callipaeda (see specific treatment schedules under “Amounts to be administered and administration route”),

Crenosoma vulpis (Reduction of the level of infection),

Angiostrongylus vasorum (Reduction of the level of infection by immature adult (L5) and adult parasite stages; see specific treatment and disease prevention schedules under section “ Amounts to be administered and administration route”).

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

Contra-indications

Milpro 2.5mg/25mg for small dogs and puppies -

Do not use in puppies of less than 2 weeks of age and/or weighing less than 0.5 kg.

Milpro 12.5mg/125mg for dogs -

Do not use in dogs weighing less than 5 kg

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

See also point "Special precautions for use"

Special warnings for each target species

In order to develop an effective worm control programme local epidemiological information and the living conditions of the dog should be taken into account and therefore it is recommended to seek professional advice.

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

It is recommended to treat all the animals in the same household concomitantly.

When *Dipylidium caninum* infection is present, concomitant treatment against intermediate hosts, such as fleas and lice, should be considered to prevent reinfection.

Special precautions for use

Special precautions for safe use in the target species

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 the product 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 (see also section "Overdose").

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 the product, 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 the product.

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.

The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after use.

In the event of accidental ingestion of the tablets, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the doctor.

Do not handle this product in case of known hypersensitivity to the active substances or to any of the excipients.

Other Precautions

Echinococcosis represents a hazard for humans. As echinococcosis is a notifiable disease to the World Organisation for Animal Health (WOAH), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

Adverse reactions

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction
	Systemic disorder (e.g. Leth
	Neurological disorder (e.g.
	Digestive tract disorder (e.g

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

Pregnancy and lactation:

In a study, this combination of active substances was demonstrated to be well tolerated in breeding bitches, including during pregnancy and lactation.

As a specific study with this product has not been performed, use during pregnancy and lactation only according to a benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

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

Amounts to be administered and administration route

Oral use.

Minimum recommended dose rate: 0.5 mg of milbemycin oxime and 5 mg of praziquantel per kg are given once orally.

The product should be administered with or after some food.

The tablets are meat flavoured and easy to administer (usually dogs and puppies will accept them voluntarily even without any food).

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

Weight	**Milpro 2.5mg/25mg tablets for small dogs and puppies**
0.5 - 1 kg	½ tablets
>1 - 5 kg	1 tablet
>5 - 10 kg	2 tablets

Weight	**Milpro 12.5mg/125mg tablets for dogs**
5 - 25 kg	1 tablet
>25 - 50 kg	2 tablets
>50 - 75 kg	3 tablets

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

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

In endemic areas administration of the product every four weeks will prevent angiostrongylosis by reducing immature adult (L5) and adult parasite burden, where concomitant treatment against cestodes is indicated.

For the treatment of *Thelazia callipaeda*, milbemycin oxime should be given in 2 treatments, seven days apart. Where concomitant treatment against cestodes is indicated, the product can replace the monovalent product containing milbemycin oxime alone.

Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No other signs than those observed at the recommended dose have been observed.

See above under adverse reactions

Withdrawal periods

Not applicable

Pharmacological particulars

Pharmacodynamic properties

Milbemycin oxime belongs to the group of macrocyclic lactones, isolated from the fermentation of *Streptomyces hygroscopicus var. aureolacrimosus*. It is active against mites, against larval and adult stages of nematodes as well as against larvae of *Dirofilaria immitis*. The activity of milbemycin is related to its action on invertebrate neurotransmission: Milbemycin oxime, like avermectins and other milbemycins, increases nematode and insect membrane permeability to chloride ions via glutamate-gated chloride ion channels (related to vertebrate GABAα and glycine receptors). This leads to hyperpolarisation of the neuromuscular membrane and flaccid paralysis and death of the parasite.

Praziquantel is an acylated pyrazino-isoquinoline derivative. Praziquantel is active against cestodes and trematodes. It modifies the permeability for calcium (influx of Ca2+) in the membranes of the parasite inducing an imbalance in the membrane structures, leading to membrane depolarisation and almost instantaneous contraction of the musculature (tetany), rapid vacuolization of the syncytial tegument and subsequent tegumental disintegration (blebbing), resulting in easier expulsion from the gastrointestinal tract or death of the parasite.

Pharmacokinetic properties

After oral administration of praziquantel in the dog, peak serum levels of parent are rapidly attained (Tmax approximately 0.5-4 hours) and decline quickly (t1/2 approximately 1.5 hours); there is a substantial hepatic first-pass effect, with very rapid and almost complete hepatic biotransformation, principally to monohydroxylated (also some di- and tri-hydroxylated) derivatives, which are mostly glucuronide and/or sulfate conjugated before excretion. Plasma binding is about 80%. Excretion is fast and complete (about 90% in 2 days); the principal route of elimination is renal.

After oral administration of milbemycin oxime in dogs, peak plasma levels occur at about 2-4 hours, and decline with a half-life of the unmetabolised milbemycin oxime of 1-4 days. Bioavailability is about 80%.

In the rat, metabolism appears to be complete although slow, since unchanged milbemycin oxime has not been found in urine or feces. Main metabolites in the rat are monohydroxylated derivatives,

attributable to hepatic biotransformation. In addition to relatively high liver concentrations, there is some concentration in fat, reflecting its lipophilicity

Pharmaceutical particulars

Major incompatibilities

Not applicable

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging (for half tablets): 6 months

Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.

Half tablets should be stored in the original blister and be used for the next administration (Small Dogs and Puppies).

Keep the blister in the outer carton.

Immediate packaging

Aluminium/ Aluminium blister pack (Oriented polyamide/Aluminium/Polyvinyl chloride sealed to Aluminium film).

Available pack sizes:

1 box of 2 tablets containing 1 blister of 2 tablets (divisible per tablet)

1 box of 4 tablets containing 2 blisters of 2 tablets (divisible per tablet)

1 box of 24 tablets containing 12 blisters of 2 tablets (divisible per tablet)

1 box of 48 tablets containing 24 blisters of 2 tablets (divisible per tablet)

Not all pack sizes may be marketed.

Disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Marketing Authorisation Holder (if different from distributor)

NOAH Compendium

Virbac

1ère avenue 2065m – L.I.D.

06516 Carros

France

Marketing Authorisation Number

Milpro 2.5mg/25mg

Vm 05653/5065

Milpro 12.5mg/125mg

Vm 05653/5066

Significant changes

Date of the first authorisation or date of renewal

15 July 2014

Date of revision of the text

October 2025

Any other information

Nil

Legal category

Legal category:POM-V

GTIN

GTIN description: Milpro 2.5mg/25mg film-coated tablets for small dogs and puppies 24 tablets

GTIN:03597133066500

GTIN description: Milpro 12.5mg/125mg film-coated tablets for dogs 4 tablets

GTIN:03597133066517

GTIN description: Milpro 12.5mg/125mg film-coated tablets for Dogs 48 tablets

GTIN:03597133066524