

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbetab 12.5 mg/125 mg Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablets contains:

Active substances:

Milbemycin oxime	12.5 mg
Praziquantel	125 mg

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, microcrystalline
Croscarmellose sodium
Povidone K30
Lactose monohydrate
Silica, colloidal anhydrous
Magnesium stearate
Talc
Grilled Meat flavour
Yeast Extract

A white to off white round shaped tablet with a breakline on one side.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

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:

Ancylostoma caninum

Toxocara canis

Toxascaris leonina

Trichuris vulpis

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 SPC point “3.9 Amounts to be administered and administration route”)

Thelazia callipaeda (see specific treatment schedule under section 3.9 “Amounts to be administered and administration route”)

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

3.3 Contraindications

Do not use in dogs weighing less than 5 kg.

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

See also section 3.5 “Special precautions for use”.

3.4 Special warnings

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 veterinary medicinal 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 in point 3.10).

3.5 Special precautions for use

Special precautions for safe use in the target species

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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product.

No studies have been performed with severely debilitated dogs or individuals with seriously compromised kidney or liver function. The veterinary medicinal 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, tape worm 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.

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.

Special precautions for the protection of the environment

Not applicable

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 (e.g. experts or institutes of parasitology).

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (such as Diarrhoea, Drooling, Emesis) Hypersensitivity reaction Neurological disorders (such as Ataxia, Convulsions, Muscle tremors) Systemic disorders (such as Anorexia, Lethargy)
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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.

3.7 Use during pregnancy, lactation or lay

The veterinary medicinal product may be used in breeding dogs including pregnant and lactating bitches.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Oral use.

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

The veterinary medicinal product should be administered with or after some food.

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

Weight	Tablets
> 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 veterinary medicinal 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 veterinary medicinal product and continue with the monovalent product containing milbemycin oxime alone, for the remaining three weekly treatments.

In endemic areas administration of the veterinary medicinal 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 veterinary medicinal product can replace the monovalent product containing milbemycin oxime alone.

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

No other signs than those observed at the recommended dose have been observed (see 3.6)

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AB51 (milbemycin oxime, combinations)

4.2 Pharmacodynamics

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 GABAA 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 Ca^{2+}) 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.

4.3 Pharmacokinetics

After oral administration of praziquantel in the dog, peak serum levels of parent are rapidly attained (T_{max} approximately 0.5-4 hours) and decline quickly ($t_{1/2}$ 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 faeces. 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months
Any unused half tablets should be returned to the open blister and discarded after 4 weeks.

5.3 Special precautions for storage

Do not store above 25°C.
Keep blister in the outer carton to protect from light.

5.4 Nature and composition of immediate packaging

Blister packs made up of a cold form laminate of OPA/ALU/PVC and an aluminium foil.

Available pack sizes:

Cardboard box containing 2 tablets. (1 blister strip of 2)
Box with 2, 4, 8, 10, 20, 30, 50, 100, 200 or 500 tablets in blisters.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater. The veterinary medicinal product should not enter water courses as it 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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

7. MARKETING AUTHORISATION NUMBER

Vm 08749/5153

Vm 08749/3116

8. DATE OF FIRST AUTHORISATION

29 January 2020

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or "PID" on www.gov.uk.

Approved 16 June 2026

Gavin Hall