

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbetab 16 mg/40 mg Film-coated Tablets for Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablets contains:

Active substances:

Milbemycin oxime 16 mg

Praziquantel 40 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Core:	
Lactose Monohydrate	
Croscarmellose Sodium	
Microcrystalline Cellulose	
Povidone	
Silica, colloidal anhydrous	
Magnesium Stearate	
Coat:	
Titanium Dioxide (E171)	0.519 mg
Iron oxide Yellow	0.052 mg
Iron oxide Red	0.036 mg
Polyvinyl alcohol	
Polyethylene Glycol	
Macrogol/PEG	
Talc	
Grilled meat flavour	

Film-coated tablet.

Pink/orange, round shaped tablets with a cross break line on one side.

The tablets can be divided into halves and quarters.

3. CLINICAL INFORMATION

3.1 Target species

Cats

3.2 Indications for use for each target species

Treatment of mixed infections by immature and adult cestodes as well as nematodes of the following species:

- Cestodes:

Dipylidium caninum

Taenia spp.

Echinococcus multilocularis

- Nematodes:

Ancylostoma tubaeforme

Toxocara cati

Prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes is indicated.

The veterinary medicinal product is only indicated when use against cestodes and nematodes is indicated at the same time.

3.3 Contraindications

Do not use in cats weighing less than 1 kg.

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

See also section 3.5 "Special precautions for use".

3.4 Special warnings

In order to develop an effective worm control programme, local epidemiological information and the risk of exposure of the cat should be taken into account.

The possibility that other animals in the same household can be a source of re-infection should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.

In the absence of risk of co-infection with nematodes and cestodes, a narrow spectrum product should be used.

When infection with the cestode *D. caninum* has been confirmed, concomitant treatment against intermediate hosts, such as fleas and lice, should be discussed with a veterinarian to prevent re-infection.

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.

No studies have been performed with severely debilitated cats 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.

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

Accidental ingestion of the product may be harmful.

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 physician.

Dispose of unused tablet halves.

Wash hands after use.

Special precautions for the protection of the environment

See section 5.5.

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 people need to be obtained from the relevant competent authority.

3.6 Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (such as Diarrhoea, Emesis) Hypersensitivity reaction Neurological disorders (such as Ataxia and Muscle tremor) Systemic disorders (such as 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 product can be used in breeding cats including pregnant and lactating queens.

3.8 Interaction with other medicinal products and other forms of interaction

The concurrent use of the 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 product at the recommended dose.

Although not recommended, the concomitant use of the product with a spot-on containing moxidectin and imidacloprid at recommended dose rates following a single application was well tolerated in one laboratory study in 10 kittens.

The safety and efficacy of the concurrent use have not been investigated in field studies.

In the absence of further studies, caution should be taken in the case of concurrent use of the product with any other macrocyclic lactone. Also, no such studies have been performed with reproducing animals.

3.9 Administration routes and dosage

Oral use.

Minimum recommended dose rate: 2 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. Doing so ensures optimum protection against heartworm disease.

As per good veterinary practice, animals should be weighed to ensure accurate dosing. Underdosing could result in ineffective use and may favour resistance development.

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

Weight	Number of Tablets
1 – 2kg	¼ tablet
>2 - 4 kg	½ tablet
> 4 – 8 kg	1 tablet
> 8 - 12 kg	1½ tablets

The product can be inserted into a programme for prevention of heartworm disease if at the same time treatment against tapeworms is indicated. The product has a duration of heartworm prevention of one month. For regular prevention of heartworm disease the use of a monosubstance is preferred.

The need for and frequency of re-treatment should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

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

In case of overdose, in addition to signs observed at the recommended dose (see section 3.6 “Adverse events”) drooling was observed. This sign will usually disappear spontaneously within a day.

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: QP54A B51 (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

In the cat, praziquantel reaches peak plasma concentrations within an hour after oral administration. The half life of elimination is around 3 hours. In the dog, there is rapid hepatic biotransformation, principally to monohydroxylated derivatives. The principal route of elimination in the dog is renal. After oral administration in the cat, milbemycin oxime reaches peak plasma concentrations within 2 hours. The half life of elimination is around 13 hours ($\pm$ 9 hours). 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: 4 years.

Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Keep the blister in the outer carton in order to protect from light.

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

5.4 Nature and composition of immediate packaging

Blister packs made up of a cold form laminate of OPA/ALU/PVC of thickness 25µm/47µm/60µm with a 20µm hard tempered aluminium foil.

Available pack sizes:

1 cardboard box containing 2 tablets (1 blister strip of 2)

1 cardboard box containing 4 tablets (1 blister strip of 4 or (2 blister strips of 2)

1 cardboard box containing 10 tablets (1 blister strip of 10 or 5 blisters strips of 2)

1 cardboard box containing 20 tablets (2 blister strips of 10 or 10 blisters strips of 2)

1 cardboard box containing 50 tablets (5 blister strips of 10)

1 cardboard box containing 100 tablets (10 blister strips of 10)

Multipacks of 10 individual packs of 2 tablets

Multipacks of 10 individual packs of 20 tablets

Multipacks of 10 individual packs of 50 tablets

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

C&H Generics Ltd

7. MARKETING AUTHORISATION NUMBERS

Vm 40162/5005
Vm 40162/3005

8. DATE OF FIRST AUTHORISATION

28 February 2025

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 17 June 2026

Gavin Hall