

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemax 16 mg/40 mg film-coated tablets for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Milbemycin oxime 16 mg

Praziquantel 40 mg

Excipients:

Iron oxide (E172) 0.288 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oblong shaped, reddish to reddish brown, artificial beef flavoured film-coated tablet with a score on both sides. One side bears the imprint "KK", the other side "NA".

4. CLINICAL PARTICULARS

4.1 Target species

Cats (≥ 2 kg).

4.2 Indications for use, specifying the target species

For cats with, or at risk from mixed infections of cestodes, gastrointestinal nematodes, and/or heartworm. This veterinary medicinal product is only indicated when use against cestodes and nematodes or prevention of heartworm disease is indicated at the same time.

Cestodes

Treatment of tapeworm:

Dipylidium caninum,

Taenia spp.,

Echinococcus multilocularis.

Gastrointestinal nematodes

Treatment of:

Hookworm: *Ancylostoma tubaeforme*

Roundworm: *Toxocara cati*

Heartworm

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

4.3 Contraindications

Do not use in cats weighing less than 2 kg.

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

4.4 Special warnings for each target species

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.

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

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.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

In the absence of risk of co-infection with nematodes or cestodes, a narrow spectrum veterinary medicinal product should be used when available.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

4.5 Special precautions for use

Special precautions for use in animals

Ensure cats and kittens weighing between 0.5 kg and ≤ 2 kg receive the appropriate tablet strength (4 mg MBO/10 mg praziquantel) and the appropriate dose. See also section 4.9.

No studies have been performed with severely debilitated cats 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.

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

Wash hands after use.

In case 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.

Special precautions for the protection of the environment

See section 6.6

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).

4.6 Adverse reactions (frequency and seriousness)

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 also the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Fertility:

Can be used in breeding animals.

4.8 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.

Although not recommended, the concomitant use of the veterinary medicinal 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 with any other macrocyclic lactone. Also, no such studies have been performed with breeding animals.

4.9 Amount(s) to be administered and administration route

Oral use.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Minimum recommended dose rate: 2 mg of milbemycin oxime and 5 mg of praziquantel per kg are given as a single dose. The veterinary medicinal product should be administered with or after some food. Doing so ensures optimum protection against heartworm disease.

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

Weight	Tablets
2 - 4 kg	½ tablet
> 4 - 8 kg	1 tablet
> 8 - 12 kg	1½ tablets

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of overdose, in addition to signs observed at the recommended dose (see section 4.6 “Adverse reactions”), drooling was observed. This sign will usually disappear spontaneously within a day.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides and repellants
- endectocides

ATC Vet Code: QP54AB51 (milbemycin oxime, combinations)

5.1 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 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.

5.2 Pharmacokinetic particulars

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 (± 9 hours). 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:

Cellulose, microcrystalline

Croscarmellose sodium

Povidone

Lactose monohydrate

Silica, colloidal anhydrous

Magnesium stearate

Coat:

Hypromellose

Macrogol

Talc

Iron oxide red

Artificial beef flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

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

Shelf-life after first opening of the immediate packaging: 6 months (half tablet).

6.4 Special precautions for storage

Do not store above 25 °C.

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

6.5 Nature and composition of immediate packaging

PVC/PE/PVdC/aluminium blisters in an outer cardboard box.

Cardboard box with 1 blister of 2 or 4 film-coated tablets.

Cardboard box with 1, 2, 5 or 10 blisters of 10 film-coated tablets.

Not all pack sizes may be marketed

6.6 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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

8. MARKETING AUTHORISATION NUMBER

Vm 00879/5026

9. DATE OF FIRST AUTHORISATION

17 April 2003

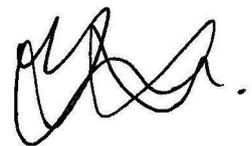
10. DATE OF REVISION OF THE TEXT

September 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 15 April 2024