

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MILBEMAX Film-coated tablets for small cats and kittens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:

Active substances:

Milbemycin oxime	4 mg
Praziquantel	10 mg

Excipients QS one divisible tablet of 132.5 mg
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Oblong shaped, beige to brown, artificial beef flavoured tablet with a score on both sides. One side bears the imprint "BC", the other side "NA".

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

In cats: treatment of mixed infections by immature and adult cestodes **and** 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.

4.3 Contraindications

Do not use in cats of less than 6 weeks of age and/or weighing less than 0.5 kg.

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals

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

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 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

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.

4.6 Adverse reactions (frequency and seriousness)

In very rare occasions, especially in young cats, systemic signs (such as lethargy), neurological signs (such as ataxia and muscle tremors) and/or gastrointestinal signs (such as emesis and diarrhoea) have been observed after administration of the veterinary medicinal product.

4.7 Use during pregnancy, lactation or lay

MILBEMAX can be used in breeding cats including pregnant and lactating queens.

4.8 Interaction with other medicinal products and other forms of interaction

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.

Although not recommended, the concomitant use of MILBEMAX 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.

4.9 Amounts to be administered and administration route

Minimum recommended dose rate: 2 mg of milbemycin oxime and 5 mg of praziquantel per kg are given orally as a single dose. The 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
0.5 - 1 kg	½ tablet
> 1 - 2 kg	1 tablet

MILBEMAX can be inserted into a programme for prevention of heartworm disease if at the same time treatment against tapeworms is indicated. MILBEMAX has a duration of heartworm prevention of one month. For 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 4.6), 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

ATCvet 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 GABA_A 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.

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 (\pm 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

Artificial beef flavour

6.2 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

6.4. Special precautions for storage

Do not store above 25°C.

Keep blister in the outer carton to protect from light.

6.5 Nature and composition of immediate packaging

PVC/PE/PVdC/aluminium blister

Available pack sizes:

Box with 2 tablets in blister
Box with 4 tablets in blister
Box with 10 tablets in blister
Box with 20 tablets in blister
Box with 50 tablets in blister
Box with 100 tablets in blister

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

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

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

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Lilly House
Priestly Road
Basingstoke
Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4041

9. DATE OF FIRST AUTHORISATION

17 April 2003

10. DATE OF REVISION OF THE TEXT

March 2016



16 March 2016

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MILBEMAX Film-coated tablets for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:

Active substances:

Milbemycin oxime	16 mg
Praziquantel	40 mg

Excipients:

Iron oxide (E172)	0.288 mg
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Excipients QS one divisible tablet of 132.5 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Oblong shaped, reddish to reddish brown, artificial beef flavoured 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.

4.2 Indications for use, specifying the target species

In cats: treatment of mixed infections by immature and adult cestodes **and** 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.

4.3 Contraindications

Do not use in cats weighing less than 2 kg.

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals

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

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.

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concurrent use of the product with any other macrocyclic lactone. Also, no such studies have been performed with reproducing animals.

4.9 Amounts to be administered and administration route

Minimum recommended dose rate: 2 mg of milbemycin oxime and 5 mg of praziquantel per kg are given orally as a single dose. The 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

MILBEMAX can be inserted into a programme for prevention of heartworm disease if at the same time treatment against tapeworms is indicated. MILBEMAX has a duration of heartworm prevention of 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 4.6), 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

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5.2 Pharmacokinetic particulars

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Macrogol

Talc

Iron oxide red

Artificial beef flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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6.4. Special precautions for storage

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