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

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

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.
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.

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. 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 (1/2 or 1 tablet) for the corresponding weight band (1/2 tablet for cats weighing 0.5 to 1 kg ; 1 tablet for cats weighing >1 to 2 kg – 1 tablet).

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 physician.

4.6 Adverse reactions (frequency and seriousness)

In very rare occasions, especially in young cats, hypersensitivity reactions, 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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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
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 section 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
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 $GABA_A$ 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, prinicipally 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, microcristalline
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

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 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 veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. MILBEMAX 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
United Kingdom

8. MARKETING AUTHORISATION NUMBER

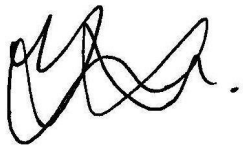
Vm 00879/4042

9. DATE OF FIRST AUTHORISATION

17 April 2003

10. DATE OF REVISION OF THE TEXT

September 2020



Approved: 16 September 2020