PACKAGE LEAFLET

MILBEMAX, film-coated tablets for cats
MILBEMAX, film-coated tablets for small cats and kittens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Manufacturing Authorisation Holder:
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

Manufacturer responsible for batch release:
Elanco France S.A.S.,
26 rue de la Chapelle
F-68330 Huningue
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT
MILBEMAX® film-coated tablets for cats
MILBEMAX® film-coated tablets for small cats and kittens
milbemycin oxime / praziquantel
Broad spectrum wormer

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

MILBEMAX film-coated tablets for cats, small cats, and kittens are available in 2 different sizes:

Name of tablet (Type of tablet)	Milbemycin oxime per tablet	Praziquantel per tablet	Excipients q.s. to
MILBEMAX tablets for small cats and kittens (beige to brown, artificial beef flavoured, oblong, divisible)	4 mg	10 mg	132,5 mg
MILBEMAX tablets for cats (reddish to reddish brown, artificial beef flavoured, oblong, divisible)	16 mg	40 mg	132,5 mg

4. INDICATION(S)

MILBEMAX is indicated in the cat for 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*

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

5. CONTRAINDICATIONS

Do not use the '**tablets for small cats and kittens'** in cats of less than 6 weeks of age and/or weighing less than 0.5 kg
Do not use the '**tablets for cats'** in cats weighing less than 2 kg.

6. ADVERSE REACTIONS

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

MILBEMAX tablets are administered at a minimum recommended dose rate of 2 mg milbemycin oxime and 5 mg praziquantel per kg body weight.

Milbemax is given-by oral administration 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	MILBEMAX tablets for small cats and kittens	MILBEMAX tablets for cats
0,5 - 1 kg	½ tablet (oblong, beige to brown)	
> 1 – 2 kg	1 tablet (oblong, beige to brown)	
>2 – 4 kg		½ tablet (oblong, reddish to reddish brown)
>4 – 8 kg		1 tablet (oblong, reddish to reddish brown)
>8 – 12 kg		1½ tablet (oblong, reddish to reddish brown)

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.

9. ADVICE ON CORRECT ADMINISTRATION

MILBEMAX is given as a single dose by oral administration with or after some food. Doing so ensures optimum protection against heartworm disease.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Keep the blister in the outer carton in order to protect from light.

Do not use after the expiry date stated on the blister and carton after EXP. The expiry date refers to the last day of that month.
In use shelf-life for half tablets is 6 months.

12. SPECIAL WARNING(S)

For animal treatment only.

Special warnings for each target species:
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. Contact your local veterinarian for advice.

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.
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 and show the doctor the pack and/or the leaflet.

Pregnancy and lactation:
The product can be used in breeding animals including pregnant and lactating queens.

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.

Overdose (symptoms, emergency procedures, antidotes):
In case of overdose, in addition to signs observed at the recommended dose (see 6), drooling was observed. This sign will usually disappear spontaneously within a day.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 16 September 2020