1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milipraz 4 mg/10 mg film-coated tablets for small cats and kittens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Milbemycin oxime	4.0 mg
Praziquantel	10.0 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	
Cellulose, microcrystalline	
Microcrystalline Cellulose	
Povidone K30	
Silica, colloidal anhydrous	
Magnesium Stearate	
Coat:	
Titanium Dioxide (E171)	0.486 mg
Hypromellose	
Macrogol 4000	
Grilled meat flavour	

White to off-white oval shaped film-coated tablet with break lines on both sides.
The tablets can be divided into halves.

3. CLINICAL INFORMATION

3.1 Target species

Cats (≥ 0.5 - 2 kg).

3.2 Indications for use for each 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 tapeworms:
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.

3.3 Contraindications

Do not use in cats of less than 6 weeks of age and/or weighing less than 0.5 kg.
Do not use in case of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

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.
Resistance of *Dipylidium caninum* to praziquantel and resistance of *Dirofilaria immitis* to macrocyclic lactones have been reported.
It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method.
Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

As the tablets are flavoured, they should be stored in a safe place out of the reach of animals.

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

People with known hypersensitivity to milbemycin oxime/praziquantel should avoid contact with the veterinary medicinal product.

Avoid accidental ingestion.
This veterinary medicinal product may be harmful when ingested, particularly for children.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Unused tablet parts should be discarded. The product should be stored in a safe place.

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 persons need to be obtained from the relevant competent authority (e.g. experts or institutes of parasitology).

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)

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

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Fertility:
Can be used in breeding animals

3.8 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 of the veterinary medicinal product with any other macrocyclic lactone. Also, no such studies have been performed with breeding animals.

3.9 Administration routes and dosage

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.

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

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

Weight	Number of Tablets
0.5 - 1 kg	½ tablet
> 1 – 2 kg	1 tablet

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 product has a duration of heartworm prevention of one month. For regular prevention of heartworm disease, the use of a narrow spectrum product containing a single active substance is preferred.

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

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 $GABA_A$ 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 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 3 hours after oral administration. The half life of elimination is around 5 hours.

After oral administration in the cat, milbemycin oxime reaches peak plasma concentrations within 3 hours. The half life of elimination is around 47 hours.

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.
Unused tablet parts should be discarded.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Blister packs made up of a laminate of OPA/ALU/PVC with a hard tempered aluminium foil in a cardboard box.

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 or household waste.

The veterinary medicinal product should not enter water courses as milbemycin oxime and praziquantel 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

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/174/002

8. DATE OF FIRST AUTHORISATION

08/11/2024

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07/05/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).