

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milgusto CHEWABLE 16 mg/40 mg film-coated tablets for cats weighing at least 2 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Active substances:

Milbemycin oxime	16 mg
Praziquantel	40 mg

Excipients:

Iron Oxide, yellow (E172)	0.03 mg
Iron Oxide, red (E172)	0.12 mg
Iron Oxide, black (E172)	0.05 mg
Titanium dioxide (E171)	0.21 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Brown, oval, biconvex film-coated tablets with score line on one side.

The tablets can be divided into halves.

4. CLINICAL PARTICULARS

4.1 Target Species

Cats (weighing at least 2 kg).

4.2 Indications for use, specifying the target species

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.

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

4.4 Special warnings for each target species

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

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, and it is recommended to seek professional (e. g. veterinary) advice.

When *D. caninum* infection is present, concomitant treatment against intermediate hosts, such as fleas and lice, should be considered to prevent re-infection.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

4.5 Special precautions for use

Special precautions for use in animals

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.

Ensure cats and kittens weighing between 0.5 kg and ≤ 2 kg receive the appropriate tablet strength (4 mg milbemycin oxime/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).

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

Accidental ingestion of a tablet by a child may be harmful. In order to prevent children from accessing the veterinary medicinal product, tablets should be administered and stored out of sight and reach of children.

Part tablets should be returned to the open blister pocket and inserted into the outer carton.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

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):	Hypersensitivity reaction Systemic disorders (e.g. lethargy)* Neurological disorders (e.g. ataxia, muscle tremors)* Gastrointestinal disorders (e.g. emesis, diarrhoea)*
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*Especially in young cats.

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 the national competent authority via the national reporting system. See the package leaflet for contact details.

4.7 Use during pregnancy and lactation

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Fertility:

Can be used in breeding cats.

4.8 Interaction with other medicinal products and other forms of interaction

No interactions were observed when the recommended dose of the macrocyclic lactone selamectin was administered during treatment with milbemycin oxime and praziquantel at the recommended dose. In the absence of further studies, caution should be taken in the case of concurrent use of the veterinary medicinal product and other macrocyclic lactones. Also, no such studies have been performed with reproducing animals.

4.9 Amounts to be administered and administration route

Oral use.

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 orally 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:

Body weight	Film-coated tablets for cats
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. For the prevention of heartworm disease: the veterinary medicinal product kills *Dirofilaria immitis* larvae up to one month after their transmission by mosquitoes. 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 may be observed. This sign will usually disappear spontaneously within a day.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides, Macrocyclic lactones, milbemycin, combinations

ATCvet code: QP54AB51

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 cats under fed condition, praziquantel reaches peak plasma concentrations within 3 hours after oral administration.

The half life of elimination is around 2 hours.

After oral administration in cats under fed condition, milbemycin oxime reaches peak plasma concentrations within 5 hours. The half life of elimination is around 43 hours ($\pm$ 21 hours).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:

Cellulose, microcrystalline

Lactose monohydrate

Povidone

Croscarmellose sodium

Silica, colloidal anhydrous

Magnesium stearate

Coat:

Hypromellose

Talc

Propylene glycol

Titanium dioxide (E171)

Liver Flavour

Yeast powder

Iron Oxide, yellow (E172)

Iron Oxide, red (E172)

Iron Oxide, black (E172)

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 for halved tablets after first opening the immediate packaging: 6 months.

6.4. Special precautions for storage

Store in the original package in order to protect from moisture.

This veterinary medicinal product does not require any special temperature storage conditions.

Store halved tablets below 25°C in the original blister and use for the next administration.

Keep the blister in the outer carton.

6.5 Nature and composition of immediate packaging

Blister packs consisting of cold formed OPA/Al/PVC foil and aluminium foil.

Cardboard box with 1 blister of 2 tablets.

Cardboard box with 1 blister of 4 tablets.

Cardboard box with 12 blisters, each blister contains 4 tablets (total 48 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 milbemycin oxime may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

8. MARKETING AUTHORISATION NUMBER

Vm 01656/5087

9. DATE OF FIRST AUTHORISATION

05 April 2019

10. DATE OF REVISION OF THE TEXT

July 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall

Approved: 19 November 2024