SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbeguard Duo 16 mg / 40 mg film-coated tablets for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substances:

Milbemycin oxime	16 mg
Praziquantel	40 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film-coated tablet.
Flavoured oblong tablet, red to reddish brown, scored on one side. The tablet can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1 Target species

Cats (weighing at least 2 kg)

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.
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

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 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.
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.
The use of this product should take into account local information about susceptibility of the target parasites, where available.
In the absence of risk of co-infection with nematodes or cestodes, a narrow spectrum product should be used when available.

4.5 Special precautions for use

i). Special precautions for use in animals
Ensure cats and kittens weighing between 0.5 kg and ≤2 kg receive the correct dose of the 4/10 mg strength tablet.
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.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

ii). Special precautions to be taken by the person administering the veterinary medicinal product to animals
This veterinary medicinal product may be harmful when ingested, particularly for children. To avoid accidental ingestion, the product should be stored out of sight and reach of children. Any unused part of tablet should be stored in the opened blister, inside the outer packaging and always be used at the next administration.
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.
Wash hands after use.

iii). Other precautions
Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow up and on the safeguard of persons need to be obtained from the relevant competent authority.

4.6 Adverse reactions (frequency and seriousness)

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[1] Lethargy[1], Anorexia[1] Muscle tremor, Ataxia[1] Emesis[1], Diarrhoea[1]

[1]: especially in young cats

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has been established during pregnancy and lactation.
Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

The concurrent use of the product with selamectin is well tolerated. No interactions were observed when the recommended dose of the macrocyclic lactone selamectin was administered during the treatment with the product at the recommended dose.
Although not recommended, the concomitant use of the 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 product with any other macrocyclic lactone. Also, no such studies have been performed with reproducing animals.

4.9 Amount(s) to be administered and administration route

Oral use.
Minimum recommended dose rate: 2 mg of milbemycin oxime and 5 mg of praziquantel per kg are given orally as a single dose.
Animals should be weighed to ensure accurate dosing. Depending on the bodyweight of the cat, the practical dosing is as follows:

Body weight (kg)	16/40 tablets
2-4	1/2
>4-8	1
>8-12	1+1/2

They should be administered with or after some food.
The product can be inserted into a program 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 monosubstance is preferred.

Underdosing could result in ineffective use and may favour resistance development.
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of overdose, in addition to signs observed at the recommended dose (see section 3.6), drooling was observed. This sign will usually disappear spontaneously within a day.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: milbemycin oxime combinations

ATC Vet 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 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 GABAA 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. 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 depolarization andalmost 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, plasma concentrations of praziquantel reach a peak of 1125 µg/L within 2 hours after oral administration. The half-life of elimination is around 4 hours. After oral administration in the cat, plasma concentrations of milbemycin oxime reach a peak of 1696 µg/L within 3 hours. The half-life of elimination is around 78 hours. 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:
Povidone
Croscarmellose sodium
Artificial Chicken flavour
Lactose monohydrate
Cellulose microcrystalline
Silica, colloidal anhydrous
Magnesium stearate
Coat:
Polyvinyl alcohol (E1203)
Macrogol (E1521)
Talc (E553b)
Ponceau 4R (E124)
Sunset yellow (E110)
Titanium dioxide (E171)

6.2 Major Incompatibilities

Not applicable

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:30 months
Shelf life for halved tablet after first opening the blister: 6 months

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions. Halved tablets should be stored in the original blister and be used for the next administration.

6.5 Nature and composition of immediate packaging

Polyamide-Aluminium-Polyvinyl chloride / aluminium heat sealed blisters.
I Cardboard box with 1 blister of 2 tablets (2 tablets).
II Cardboard box with 2 blisters of 2 tablets (4 tablets).
III Cardboard box with 5 blisters of 2 tablets (10 tablets).
IV Cardboard box with 12 blisters of 2 tablets (24 tablets).
V Cardboard box with 24 blisters of 2 tablets (48 tablets).
VI Cardboard box with 50 blisters of 2 tablets (100 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 or <household waste>.
The veterinary medicinal product should not enter water courses as this 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.

7 MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

8. MARKETING AUTHORISATION NUMBER

Vm 15052/5039

9. DATE OF FIRST AUTHORISATION

26 October 2023

10. DATE OF REVISION OF THE TEXT

October 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription except for some pack sizes.
Not all pack sizes may be subject to prescription.
(Concerned pack-sizes to be completed nationally)

Approved 26 October 2023