Summary of Product Characteristics

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

**MILBEMAX®**
Film-coated tablets for small cats and kittens

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablet contains:

Active substances:
- Milbemycin oxime 4 mg
- Praziquantel 10 mg

Excipients:
- Titanium dioxide (E171) 0.608 mg
- Iron oxide (E172) 0.016 mg

Excipients QSP one divisible tablet of 130 mg
For a full list of excipients, see section 6.1

3. **PHARMACEUTICAL FORM**

Film-coated tablet
Oblong shaped, pink, with a score on one side. One side bears the imprint “BC”, the other side “NA”.

4. **CLINICAL PARTICULARS**

4.1 **Target species**

Cats

4.2 **Indications for use**
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 Contra-indications

Do not use in cats of less than 6 weeks of age and/or weighing less than 0.5 kg

### 4.4 Special warnings

None

### 4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

#### Special precautions for use in animals

As per good veterinary practice, animals should be weighed to ensure accurate dosing

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 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 doctor.
4.6 **Adverse reactions (frequency and seriousness)**

"In very rare occasions, especially in young cats, 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."

4.7 **Use during pregnancy and lactation**

MILBEMAX can be used in breeding cats including pregnant and lactating queens.

4.8 **Interaction with other medicaments 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. In the absence of further studies, caution should be taken in the case of concurrent use of MILBEMAX and other macrocyclic lactones. 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 once orally.

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:

<table>
<thead>
<tr>
<th>Weight</th>
<th>Tablets</th>
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<tbody>
<tr>
<td>0.5 - 1 kg:</td>
<td>½ tablet</td>
</tr>
<tr>
<td>&gt; 1 – 2 kg:</td>
<td>1 tablet</td>
</tr>
</tbody>
</table>

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 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: QP54A B51

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\textsubscript{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-isouquinoline derivative. Praziquantel is active against cestodes and trematodes. It modifies the permeability for calcium (influx of Ca\textsuperscript{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.

5.2. Pharmacokinetic properties

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, principally 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, microcrystalline
- Croscarmellose sodium
- Povidone
- Lactose monohydrate
- Silica, colloidal anhydrous
- Magnesium stearate

Coat:
- Hypromellose
- Macrogol
- Talc
- Titanium dioxide
- Iron oxide red

6.2. 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 30°C
Keep blister in the outer carton to protect from light

6.5. Nature and composition of immediate packaging

PVC/PE/PVdC/aluminium blister

Available package 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 product or waste material should be disposed of in accordance with national requirements. The product should not come into contact with (IE’s proposal) water courses as this may be dangerous for fish and other aquatic organisms.

7. **MARKETING AUTHORITY**

Novartis Animal Health Inc.

8. **MARKETING AUTHORIZATION NUMBER(S)**

{National MA Number(s)}

9. **DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION**

{DD MMM YYYY}

10. **DATE OF REVISION OF THE TEXT**

{MMM YYYY}

**PROHIBITION OF SALE, SUPPLY AND/OR USE**