ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milprazin 16 mg/40 mg film-coated tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains: milbemycin oxime 16 mg and praziquantel 40 mg.

3. PACKAGE SIZE

2 tablets
4 tablets

4. TARGET SPECIES

Cats (weighing at least 2 kg)

5. INDICATIONS

Only for those countries where the product is available without prescription:

Flavoured broad spectrum anthelmintic
Treatment of mixed infections by immature and adult tapeworms and roundworms

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

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

9. SPECIAL STORAGE PRECAUTIONS

Store in the original blister in order to protect from moisture.
Halved tablets should be stored below 25°C in the original blister and be used for the next administration.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/3094

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milprazin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

16 mg/40 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

KRKA

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each film-coated tablet contains:

Active substances:

Milbemycin oxime	16 mg
Praziquantel	40 mg

Excipients:

Titanium dioxide (E171)	0.51 mg
Iron Oxide, red (E172)	0.20 mg

Brown red, oval, biconvex film-coated tablets with score line on one side.
The tablets can be divided into halves.

3. Target species

Cats (weighing at least 2 kg)

4. Indications for use

Treatment of mixed infections by immature and adult tapeworms and roundworms of the following species:

- Tapeworms:
Dipylidium caninum
Taenia spp.
Echinococcus multilocularis

- Roundworms:
Ancylostoma tubaeforme
Toxocara cati

Prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against tapeworms is indicated.

5. 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.

6. Special warnings

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

In order to effectively control worm infection local epidemiological information (information about presence of parasites and their susceptibility to particular worming treatments) and the living conditions of the cat should be taken into account, and it is recommended to seek professional (e. g. veterinary) advice.

When infection with tapeworm *D. caninum* 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 (drugs acting against worms) may develop following frequent, repeated use of an anthelmintic of that class.

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.
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:
In case of accidental ingestion, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.
Part tablets should be returned to the open blister pocket and inserted into the outer carton.

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).

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

Fertility:
Can be used in breeding cats.

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.

Overdose:
In case of overdose, in addition to signs observed at the recommended dose (see »Adverse events«), drooling may be observed. This sign will usually disappear spontaneously within a day.

7. Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction Systemic disorders (e.g. lethargy)* Neurological disorders (e.g. ataxia (incoordination), muscle tremor)* Digestive tract disorders (e.g. emesis, diarrhoea)*

*Especially in young cats.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

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

9. Advice on correct administration

The veterinary medicinal product should be administered with or after some food. Doing so ensures optimum protection against heartworm disease.
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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original blister in order to protect from moisture.
This veterinary medicinal product does not require any special temperature storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after Exp. The expiry date refers to the last day of that month.

Shelf life for halved tablets after first opening the immediate packaging: 6 months. Halved tablets should be stored below 25°C in the original blister and be used for the next administration.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as milbemycin oxime 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01656/3094

Box with 1 blister of 2 tablets.
Box with 1 blister of 4 tablets.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
KRKA - FARMA d.o.o., V. Holjevca 20/E, 10450 Jastrebarsko, Croatia

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information

Approved 22 June 2024
Gavin Hall