A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbactor 4 mg/10 mg film-coated tablets for small cats and kittens weighing at least 0.5 kg

Milbemycin oxime/praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains:
Active substances:

Milbemycin oxime	4 mg
Praziquantel	10 mg

3. PHARMACEUTICAL FORM

Film-coated tablet

4. PACKAGE SIZE

4 tablets
48 tablets

5. TARGET SPECIES

Cats (small cats and kittens)

6. INDICATION(S)

Flavoured broad spectrum anthelmintic

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life for halved tablets after first opening the immediate packaging: 6 months.

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.
This veterinary medicinal product does not require any special temperature storage conditions.
Halved tablets should be stored below 25°C in the original blister and be used for the next administration.
Keep the blister in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4082

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Milbemycin oxime/praziquantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Milbactor 4 mg/10 mg film-coated tablets for small cats and kittens weighing at least 0.5 kg

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbactor 4 mg/10 mg film-coated tablets for small cats and kittens weighing at least 0.5 kg

Milbemycin oxime/praziquantel

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each film-coated tablet contains:

Active substances:	
Milbemycin oxime	4 mg
Praziquantel	10 mg

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

4. INDICATION(S)

Treatment of mixed infections by immature and adult cestodes and nematodes 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 cestodes is indicated.

5. 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 known cases of hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

On very rare occasions, especially in young cats, systemic signs (such as lethargy), neurological signs (such as muscle tremors and ataxia/uncoordinated movements) and/or gastrointestinal signs (such as vomiting and diarrhoea) have been observed after administration of the combination milbemycin/praziquantel.
On very rare occasions hypersensitivity reactions have been observed following administration of the product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cats (small cats and kittens).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.
Animals should be weighed to ensure accurate dosing.
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:

Weight	Film-coated tablets for small cats and kittens (brown yellow tablets)
0.5 - 1 kg	½ tablet
> 1 - 2 kg	1 tablet

9. ADVICE ON CORRECT ADMINISTRATION

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

The 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 monosubstance is preferred.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original package in order to protect from moisture. This veterinary medicinal product does not require any special temperature storage conditions.
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.
Keep the blister in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after {EXP}. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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

In order to effectively control worm infection local information about presence and susceptibilty of the parasites (epidemiological information) and the living conditions of the cat should be taken into account.

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 use in animals:
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.
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).

User warnings:
People with known hypersensitivity to the active substances or the excipients should avoid contact with the veterinary medicinal product.

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.
Wash hands after use.
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.

Pregnancy and lactation:
The veterinary medicinal product can be used in breeding cats including pregnant and lactating queens.

Interaction with other medicinal products and other forms of interaction:
The concurrent use of the milbemycin oxime and praziquantel with selamectin is well tolerated. 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 product and other macrocyclic lactones. Also, no such studies have been performed with reproducing animals.

Overdose (symptoms, emergency procedures, antidotes):
In case of overdose, in addition to signs observed at the recommended dose (see 6), drooling may be observed. This sign will usually disappear spontaneously within a day.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.
The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2021

15. OTHER INFORMATION

Box with 1 blister of 4 tablets.
Box with 12 blisters, each blister contains 4 tablets.
Not all pack sizes may be marketed.

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

Approved 16 December 2021