# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**{Box}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Milbemycin oxime/praziquantel

## 2. STATEMENT OF ACTIVE SUBSTANCES

1 tablet: milbemycin oxime 16 mg and praziquantel 40 mg.

## 3. PHARMACEUTICAL FORM

Film-coated tablet

## 4. PACKAGE SIZE

2 tablets
4 tablets
48 tablets

## 5. TARGET SPECIES

Cats (weighing at least 2 kg)

## 6. INDICATION(S)

*****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
*<To be completed nationally>*

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

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

Dosage:

| Body weight | Film-coated tablets for cats |
|---|---|
| 2 - 4 kg | ½ tablet |
| more than 4 - 8 kg | 1 tablet |
| more than 8 - 12 kg | 1½ tablets |

*<To be completed nationally>*

## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

## 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.
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

Disposal: read package leaflet.

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

For animal treatment only.

*****Only for those countries where the product is available on prescription :*****
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, Slovenia

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4085

## 17. MANUFACTURER'S BATCH NUMBER

Lot

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**{NATURE/TYPE}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milprazon 16 mg/40 mg film-coated tabletsfor cats

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:
# Milprazon 16 mg/40 mg film-coated tablets for cats weighing at least 2 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:
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
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Milbemycin oxime/praziquantel

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

Each film-coated tablet contains:

| **Active substances:** | |
|---|---|
| Milbemycin oxime | 16 mg |
| Praziquantel | 40 mg |

Brown red, 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 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 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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

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

## 7. TARGET SPECIES

Cats (weighing at least 2 kg).

## 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:

| **Body weight** | **Film-coated tablets for cats** |
|---|---|
| 2 - 4 kg | ½ tablet |
| more than 4 - 8 kg | 1 tablet |
| more than 8 - 12 kg | 1½ tablets |

## 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. For the prevention of heartworm disease: the 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 PERIOD(S)

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 and the blister 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 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 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 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).
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:
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.
Part tablets should be returned to the open blister pocket and inserted into the outer carton.
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:
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.
Although not recommended, the concomitant use of milbemycin oxime and praziquantel 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 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

May 2021

## 15. OTHER INFORMATION>

Box with 1 blister of 2 tablets.
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: 21/07/21