PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milquantel 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, when stored up to 25°C.

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.

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 01656/4099

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milquantel 16 mg/40 mg film-coated tablets for cats
Milbemycin oxime/praziquantel
Milbemycinum oximum/praziquantelum (for multilingual packaging)

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.

PACKAGE LEAFLET:
Milquantel 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
KRKA - FARMA d.o.o., V. Holjevca 20/E, 10450 Jastrebarsko, Croatia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milquantel 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 case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

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 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.

7. TARGET SPECIES

Cats.

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.
Shelf life for halved tablets after first opening the immediate packaging: 6 months.
Return tablet portions to the blister pocket and store up to 25°C.
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 *D. caninum* infection 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 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.

User warnings:
Do not handle this product in case of hypersensitivity to the active substances or to any of the excipients.

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. 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

January 2022

15. OTHER INFORMATION

Box with 1 blister of 2 tablets.
Box with 1 blister of 4 tablets.
Box with 12 blisters of 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 18 March 2022