# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**{BOX}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milprazon CHEWABLE 2.5 mg/25 mg film-coated tablets for small dogs and puppies weighing at least 0.5 kg
Milbemycin oxime/praziquantel
*For memory stickers:*
Milbemycin oxime/praziquantel

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains 2.5 mg milbemycin oxime and 25.0 mg praziquantel.

## 3. PHARMACEUTICAL FORM

Film-coated tablet

## 4. PACKAGE SIZE

2 tablets
4 tablets
48 tablets

## 5. TARGET SPECIES

Dogs (small dogs and puppies)

## 6. INDICATION(S)

Flavoured broad spectrum anthelmintic
*****Only for those countries where the product is available without prescription :*****
Treatment of mixed infections by 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 | Tablets |
|---|---|
| 0.5 – 1 kg | 1/2 tablet |
| more than 1 – 5 kg | 1 tablet |
| more than 5 – 10 kg | 2 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.

## 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.
*<To be completed nationally>*

## 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

Vm 01656/5082

## 17. MANUFACTURER'S BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

**{Blister}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milprazon CHEWABLE 2.5 mg/25 mg film-coated tablets for small dogs and puppies
Milbemycin oxime/praziquantel
Milbemycinum oximum/praziquantelum (for multilingual packaging)

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

## 3. EXPIRY DATE

EXP {month/year}

## 4. BATCH NUMBER

Lot {number}

## 5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:
# Milprazon CHEWABLE 2.5 mg/25 mg film-coated tablets for small dogs and puppies 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:
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

Milprazon CHEWABLE 2.5 mg/25 mg film-coated tablets for small dogs and puppies 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:

| | **Film-coated tablets for small dogs and puppies** | **Film-coated tablets for dogs** |
|---|---|---|
| **Active substances:** | | |
| Milbemycin oxime | 2.5 mg | 12.5 mg |
| Praziquantel | 25 mg | 125 mg |

Tablets for small dogs and puppies: Pale yellowish brown, oval, biconvex, mottled, film coated tablets, scored on one side.
The tablets can be divided into equal halves.

Tablets for dogs: Pale yellowish brown, oval, biconvex, mottled, film coated tablets.

## 4. INDICATION(S)

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

- Tapeworms:
*Dipylidium caninum*
*Taenia* spp.
*Echinococcus* spp.
*Mesocestoides* spp.

- Roundworms:
*Ancylostoma caninum*
*Toxocara canis*
*Toxascaris leonina*
*Trichuris vulpis*
*Crenosoma vulpis* (Reduction of the level of infection)
*Angiostrongylus vasorum* (Reduction of the level of infection by immature adult (L5) and adult parasite stages; see specific treatment and disease prevention schedules under section “Dosage for each species, route(s) and method of administration”).

*Thelazia callipaeda* (see specific treatment schedule under section “Dosage for each species, route(s) and method of administration”).

The product can also be used in the prevention of heartworm disease (*Dirofilaria immitis*), if concomitant treatment against tapeworms is indicated.

## 5. CONTRAINDICATIONS

Do not use **tablets for small dogs and puppies** in dogs of less than 2 weeks of age and/or weighing less than 0.5 kg.
Do not use **tablets for dogs** in dogs weighing less than 5 kg.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
See also section “Special warning(s)”.

## 6. ADVERSE REACTIONS

On very rare occasions, systemic signs (such as lethargy), neurological signs (such as muscle tremors and ataxia/uncoordinated movements) and/or gastrointestinal signs (such as vomiting, diarrhoea, loss of appetite and drooling) have been observed in dogs after administration of the combination of milbemycin oxime and 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

Small dogs and puppies (weighing at least 0.5 kg).
Dogs (weighing at least 5 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: 0.5 mg of milbemycin oxime and 5 mg of praziquantel per kg are given once orally.

Depending on the bodyweight of the dog, the practical dosing is as follows:

| Body weight | Film-coated tablets for small dogs and puppies | Film-coated tablets for dogs |
|---|---|---|
| 0.5 – 1 kg | 1/2 tablet | |
| more than 1 – 5 kg | 1 tablet | |
| more than 5 – 10 kg | 2 tablets | |
| 5 – 25 kg | | 1 tablet |
| more than 25 – 50 kg | | 2 tablets |
| more than 50 – 75 kg | | 3 tablets |

In cases when heartworm disease prevention is used and at the same time treatment against tapeworm is required, the product can replace the monosubstance product for the prevention of heartworm disease.

For treatment of *Angiostrongylus vasorum* infections, milbemycin oxime should be given four times at weekly intervals. It is recommended, where concomitant treatment against tapeworms is indicated, to treat once with the product and continue with the monovalent product containing milbemycin oxime alone, for the remaining three weekly treatments.

In endemic areas administration of the product every four weeks will prevent angiostrongylosis by reducing immature adult (L5) and adult parasite burden, where concomitant treatment against tapeworms is indicated.

For the treatment of *Thelazia callipaeda*, milbemycin oxime should be given in 2 treatments, seven days apart. Where concomitant treatment against tapeworms is indicated, the product can replace the monosubstance product containing milbemycin oxime alone.

## 9. ADVICE ON CORRECT ADMINISTRATION

The product should be administered with or after some food. The product is palatable i.e. it is usually taken voluntarily by dogs (voluntary consumption on > 80% of occasions in animals studied). If the dog does not voluntarily accept the tablet, it can also be administered into the mouth.

## 10. WITHDRAWAL PERIOD(S)

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Halved tablets should be stored below 25°C in the original blister and be used for the next administration.
Store in the original package 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 the carton after {EXP}. The expiry date refers to the last day of that month.

Shelf life for halved tablets for small dogs and puppies after first opening the immediate packaging: 6 months.

## 12. SPECIAL WARNING(S)

Special warnings for each target species:
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
It is recommended to treat all the animals in the same household concomitantly.
In order to develop an effective worm control programme local epidemiological information and the risk of exposure of the dog should be taken into account, and it is recommended to seek professional (e. g. veterinary) advice.
When *D. caninum* infection is present, concomitant treatment against intermediate hosts, such as fleas and lice, should be considered to prevent re-infection.

Special precautions for use in animals:
Studies with milbemycin oxime indicate that the margin of safety in certain dogs of Collie or related breeds is less than in other breeds. In these dogs, the recommended dose should be strictly observed.
The tolerance of the product in young puppies from these breeds has not been investigated.
Clinical signs in Collies are similar to those seen in the general dog population when overdosed.
Treatment of dogs with a high number of circulating microfilariae (larvae) can sometimes lead to the appearance of hypersensitivity reactions, such as pale mucous membranes, vomiting, trembling, laboured breathing or excessive salivation. These reactions are associated with the release of proteins from dead or dying microfilariae (larvae) and are not a direct toxic effect of the product. The use in dogs suffering from microfilaremia (larvae in the blood) is thus not recommended.
In heartworm risk-areas, or in the case it is known that a dog has been travelling to and from heartworm risk regions, before using the product, a veterinary consultation is advised to exclude the presence of any pre-existing infestation of *Dirofilaria immitis*. If infestation with *Dirofilaria immitis* is diagnosed, the dog should be treated against adult parasites, adulticidal therapy is indicated before administering the product.
No studies have been performed with severely debilitated dogs or individuals with seriously impaired kidney or liver function. The product is not recommended for such animals or only according to a benefit/risk assessment by the responsible veterinarian.
In dogs less than 4 weeks old, tape worm infection is unusual. Treatment of animals less than 4 weeks old with a combination product may therefore not be necessary.
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:
Accidental ingestion of a tablet by a child may be harmful. In order to prevent children from accessing the product, tablets should be administered and stored out of sight and reach of children.
Part tablets should be returned to the open blister pocket and inserted into the outer carton.
In the event of accidental ingestion of one or more tablets, 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 (e. g. experts or institutes of parasitology).

Pregnancy and lactation:
The product may be used in breeding dogs including pregnant and lactating bitches.

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 the combination of

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):
No other signs than those observed at the recommended dose have been observed (see “Adverse events”).

## 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

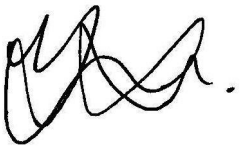
## 15. OTHER INFORMATION

Package sizes:

Cardboard box with 1 blister of 2 tablets.
Cardboard box with 1 blister of 4 tablets.
Cardboard box with 12 blisters, each blister contains 4 tablets (total 48 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: 10 September 2021