A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbactor 12.5 mg/125 mg tablets for dogs weighing at least 5 kg

Milbemycin oxime/praziquantel
Flavoured broad spectrum anthelmintic

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Active substances:

Milbemycin oxime	12.5 mg
Praziquantel	125.0 mg

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

4 tablets
48 tablets

5. TARGET SPECIES

Dogs(weighing at least 5 kg)

6. INDICATION(S)

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}

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.

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. 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 01656/4074

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbactor 12.5 mg/125 mg tablets for dogs

Milbemycin oxime/praziquantel

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 FOR:
Milbactor 2.5 mg/25 mg tablets for small dogs and puppies weighing at least 0.5 kg
Milbactor 12.5 mg/125 mg tablets for dogs weighing at least 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 2.5 mg/25 mg tablets for small dogs and puppies weighing at least 0.5 kg
Milbactor 12.5 mg/125 mg tablets for dogs weighing at least 5 kg

Milbemycin oxime, praziquantel
Flavoured broad spectrum anthelmintic

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

Each tablet contains:

	Tablets for small dogs and puppies	**Tablets for dogs**
Active substances:		
Milbemycin oxime	2.5 mg	12.5 mg
Praziquantel	25 mg	125 mg

Tablets for small dogs and puppies: Yellowish-white with brown spots, oval, biconvex tablets scored on one side.
The tablets can be divided into halves.

Tablets for dogs: Yellowish-white with brown spots, round, slightly biconvex tablets.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use tablets for small dogs and puppies in animals of less than 2 weeks of age and/or weighing less than 0.5 kg.
Do not use tablets for dogs in animals weighing less than 5 kg.
Do not use in known cases of hypersensitivity to the active substances or to any of the excipients.
See also point "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 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

Small dogs and puppies (≥ 0.5 kg).
Dogs (≥ 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	Tablets for small dogs and puppies	Tablets for dogs
0.5 – 1 kg	1/2 tablet	
>1 – 5 kg	1 tablet	
>5 – 10 kg	2 tablets	
5 – 25 kg		1 tablet
>25 – 50 kg		2 tablets
>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 monovalent 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 monovalent product containing milbemycin oxime alone.

9. ADVICE ON CORRECT ADMINISTRATION

The product should be administered with or after some food.

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 for small dogs and puppies 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 blister and 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:
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 living 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 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 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.

User warnings:
Wash hands after use.
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.
Part tablets should be returned to the open blister pocket and inserted into the outer carton.
Echinococcosis (infection with *Echinococcus* species of tapeworm) represents a hazard for humans. In case of Echinococcosis, specific guidelines on the treatment and follow up and on the safeguard of persons have to be followed. Experts or institutes of parasitology should be consulted.

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 data available.

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