B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Miziverm 2.5 mg/25 mg tablets for small dogs and puppies

2. Composition

Each tablet contains:

Active substances:

Milbemycin oxime	2.5 mg
Praziquantel	25 mg

Brown speckled round tablet with score line and characteristic smell. The tablets can be divided into two equal halves.

3. Target species

Dogs (≥ 0.5 kg).

4. Indications for use

For dogs with, or at risk from mixed infections of cestodes, gastrointestinal nematodes, eyeworm, lungworms and/or heartworm. This veterinary medicinal product is only indicated when use against cestodes and nematodes or prevention of heartworm disease/angiostrongylosis is indicated at the same time.

Cestodes
Treatment of tapeworms: *Dipylidium caninum*, *Taenia* spp., *Echinococcus* spp., *Mesocestoides* spp.

Gastrointestinal nematodes
Treatment of:
Hookworm: *Ancylostoma caninum*
Roundworms: *Toxocara canis*, *Toxascaris leonina*
Whipworm: *Trichuris vulpis*

Eyeworm
Treatment of *Thelazia callipaeda* (see specific treatment schedule under section 3.9 “Administration routes and dosage”).

Lungworms
Treatment of:
Angiostrongylus vasorum (reduction of the level of infection by immature adult (L5) and adult parasite stages; see specific treatment and prevention disease schedules under 3.9 “Administration routes and dosage”).
Crenosoma vulpis (reduction of the level of infection).

Heartworm
Prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes is indicated.

5. Contraindications

Do not use in puppies under 2 weeks of age and/or weighing less than 0.5 kg.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients. See also section "Special warnings."

6. Special warnings

Special warnings:
The possibility that other animals in the same household can be a source of re-infection should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product. It is recommended to treat all the animals living in the same household concomitantly.
When infection with the cestode *D. caninum* has been confirmed, concomitant treatment against intermediate hosts, such as fleas and lice, should be discussed with a veterinarian to prevent re-infection.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

In the absence of risk of co-infection with nematodes or cestodes, a narrow spectrum veterinary medicinal product should be used.

Resistance of *Dipylidium caninum* to praziquantel as well as cases of multi-drug resistance of *Ancylostoma caninum* to milbemycin oxime and resistance of *Dirofilaria immitis* to macrocyclic lactones have been reported.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

Special precautions for safe use in the target species:
Treatment of dogs with high number of circulating microfilariae 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 and are not a direct toxic effect of the veterinary medicinal product. The use in dogs suffering from microfilaremia 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 veterinary medicinal product, a veterinary consultation is advised to exclude the presence of any concurrent infestation of *Dirofilaria immitis*. In the case of a positive diagnosis, adulticidal therapy is indicated before administration of the veterinary medicinal product.

No studies have been performed in severely debilitated dogs or individuals with seriously compromised kidney or liver function. The veterinary medicinal product is not recommended for such animals or according to a benefit/risk assessment by the responsible veterinarian.

In dogs less than 4 weeks old, tapeworm infection is unusual. Treatment of animals less than 4 weeks old with a combination veterinary medicinal product may therefore not be necessary.
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 veterinary medicinal 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 overdose (see section "Overdose").
Poultry flavour contains poultry protein.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may be harmful when ingested, particularly for children.
Avoid accidental ingestion.
Any unused tablet parts should be returned to the open blister pocket, inserted into the outer carton and used at the next administration.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.
Poultry flavour with yeast contains poultry protein.

Special precautions for the protection of the environment:
See "Special precautions for disposal".

Other precautions:
Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (WOAH), 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:
Can be used during pregnancy and lactation.

Fertility:
Can be used in breeding animals.

Interaction with other medicinal products and other forms of interaction:
Concomitant use of the veterinary medicinal product with selamectin is well tolerated. No interactions were observed when the recommended dose of selamectin macrocyclic lactone was administered during the treatment with the recommended dose of the veterinary medicinal product. Use caution when co-administering with other macrocyclic lactones, as there are no further studies on them. Also, no similar studies have been performed in breeding animals.

Overdose:
No symptoms other than those observed after administration of the recommended dose were observed (see section Adverse events).

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (such as Diarrhoea, Drooling, Emesis) Hypersensitivity reaction Neurological disorders (such as Ataxia and Muscle tremor)

	Systemic disorders (such as Anorexia and Lethargy)

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Oral use.
Underdosing could lead to ineffective use and could promote the development of resistance.
To ensure a correct dosage, body weight should be determined as accurately as possible.
Minimum recommended dose: 0.5 mg of milbemycin oxime and 5 mg of praziquantel per kg body weight are given once. The veterinary medicinal product should be administered with or after some food.

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

Body weight	Number of tablets
0.5 - 1 kg	$^1/_2$tablet
>1–5 kg	1 tablet
> 5–10 kg	2 tablets

In the cases when heartworm disease prevention is used and at the same time treatment against tapeworms is required, the veterinary medicinal product can replace the monovalent veterinary medicinal product for the prevention of heartworm disease.

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

In endemic areas, administration of the veterinary medicinal product every four weeks will prevent a reduction of the level of infection and burden of immature adult (L5) and adult stages of *Angiostrongylus vasorum*, where concomitant treatment against cestodes is indicated.

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

9. Advice on correct administration

The veterinary medicinal product should be administered with or after some food.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as it may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

The tablets are individually packed in bags made of PET/Al/LDPE foil. The bags are placed in paper box.

Pack sizes:
2 tablets
50 tablets

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Bioveta, a. s.

Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic
Tel.: +420 517 318 911
E-mail: reklamace@bioveta.cz