# PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 1 blister of 2 tablets Box with 2 blisters of 2 tablets Box with 12 blisters of 2 tablets

# 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milpro 2.5 mg/25 mg film-coated tablets

0.5 - 10 kg

# 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Milbemycin oxime 2.5 mg Praziquantel 25 mg

## 3. PACKAGE SIZE

2 tablets

4 tablets

24 tablets

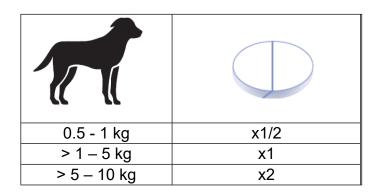
## 4. TARGET SPECIES

Dogs (small dogs and puppies)

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Oral use



#### 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp. {mm/yyyy}

## 9. SPECIAL STORAGE PRECAUTIONS

Keep the blister in the outer carton. Half tablets should be stored in the original blister and be used for the next administration.

## 10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

## 11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## 12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

**VIRBAC** 

## 14. MARKETING AUTHORISATION NUMBER

Vm 05653/5065

### 15. BATCH NUMBER

Lot {number}

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

# Blister of 2 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milpro



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

2.5 mg / 25 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

# **PACKAGE LEAFLET**

# 1. Name of the veterinary medicinal product

Milpro 2.5 mg/25 mg film-coated tablets for small dogs and puppies Milpro 12.5 mg/125 mg film-coated tablets for dogs

# 2. Composition

Each tablet contains:

#### **Active substances:**

	Milbemycin oxime	Praziquantel	Appearance
Milpro 2.5 mg/25 mg film-coated tablets for small dogs and puppies	2.5 mg	25.0 mg	Oval shaped, beige to pale brown, meat flavoured tablets with a score on both sides. The tablets can be divided into halves.
Milpro 12.5 mg/125 mg film- coated tablets for dogs	12.5 mg	125.0 mg	Round shaped, beige to pale brown meat flavoured tablets.

# 3. Target species

Dogs.

# 4. Indications for use

In dogs: treatment of mixed infections by adult tapeworms and roundworms of the following species:

Tapeworms (cestodes):

Dipylidium caninum,

Taenia spp.,

Echinococcus spp.,

Mesocestoides spp.

Roundworms (nematodes):

Ancylostoma caninum,

Toxocara canis.

Toxascaris leonina,

Trichuris vulpis,

Thelazia callipaeda (see specific treatment schedules under section "Advice on correct administration"),

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 schedule under section "Advice on correct administration").

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

#### 5. Contraindications

Milpro 2.5 mg/25 mg film-coated tablets for small dogs and puppies	Milpro 12.5 mg/125 mg film-coated tablets for dogs
Do not use in puppies of less than 2	Do not use in dogs weighing less than 5
weeks of age and/or weighing less than	kg
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:

In order to develop an effective worm control programme local epidemiological information and the living conditions of the dog should be taken into account and therefore it is recommended to seek professional advice.

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. When *Dipylidium caninum* infection is present, concomitant treatment against intermediate hosts, such as fleas and lice, should be considered to prevent reinfection.

# Special precautions for safe use in the target species:

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 overdosed (see also sub-section 'Overdose').

Treatment of dogs with a 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 administering the veterinary medicinal product.

No studies have been performed with severely debilitated dogs or individuals with seriously compromised kidney or liver function. The veterinary medicinal product is not recommended for such animals or only according to the 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 product may therefore not be necessary. The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands after use.

In case of accidental ingestion of the tablets, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the physician. Do not handle this veterinary medicinal product in case of known hypersensitivity to the active substances or to any of the excipients.

# 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.

## Pregnancy and lactation:

In a study, this combination of active substances was demonstrated to be well tolerated in breeding bitches, including during pregnancy and lactation. As a specific study with this veterinary medicinal product has not been performed, use during pregnancy and lactation only according to the benefit-risk assessment by the responsible veterinarian.

## Interaction with other medicinal products and other forms of interaction:

The concurrent use of the combination praziquantel/milbemycin oxime with selamectin is well tolerated. No interactions were observed when the recommended dose of the macrocyclic lactone selamectin was administered during treatment with the combination at the recommended dose. In the absence of further studies, caution should be taken in the case of concurrent use of the veterinary medicinal product and other macrocyclic lactones. Also no such studies have been performed with reproducing animals.

#### Overdose:

No other signs than those observed at the recommended dose have been observed (see section "Adverse events").

#### 7. Adverse events

## Dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Hypersensitivity reaction

Systemic disorder (e.g. Lethargy and Anorexia)

Neurological disorder (e.g. Muscle tremors, Ataxia (incoordination) and Convulsions)

Digestive tract disorder (e.g. Emesis (vomiting), Diarrhoea, Drooling)

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 at:

Website: <a href="https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-">https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-</a>

medicine

e-mail: adverse.events@vmd.gov.uk

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

Oral use.

Minimum recommended dose rate: 0.5 mg of milbemycin oxime and 5 mg of praziquantel per kg are given once orally.

The veterinary medicinal product should be administered with or after some food. The tablets are meat-flavoured and easy to administer (usually dogs and puppies will accept them voluntarily even without any food).

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

Weight	Milpro 2.5 mg/25 mg film- coated tablets for small dogs and puppies	Milpro 12.5 mg/125 mg film-coated 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 veterinary medicinal product can replace the monovalent product for the prevention of heartworm disease.

#### Advice on correct administration

For treatment of *Angiostrongylus vasorum* infections, 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 the monovalent 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 angiostrongylosis by reducing immature adult (L5) and adult parasite burden, where concomitant treatment against cestodes is indicated.

For the treatment of *Thelazia callipaeda*, 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 product containing milbemycin oxime alone.

# 10. Withdrawal periods

Not applicable.

# 11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.

Milpro 2.5 mg/25 mg film-coated tablets for small dogs and puppies	Milpro 12.5 mg/125 mg film-coated tablets for dogs
Keep the blister in the outer carton.	Keep the blister in the outer carton.
Half tablets should be stored in the	
original blister and be used for the next administration.	
Shelf life after first opening the	
immediate packaging (for half tablets):	
6 months.	

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister 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.

This veterinary medicinal product should not enter water courses as this 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

Vm 05653/5065 Milpro 2.5 mg/25 mg film-coated tablets for small dogs and puppies Vm 05653/5066 Milpro 12.5 mg/125 mg film-coated tablets for dogs

#### Pack sizes:

Milpro 2.5 mg/25 mg film-coated tablets for small dogs and puppies	Milpro 12.5 mg/125 mg film-coated tablets for dogs
1 box of 2 tablets containing 1 blister of 2 tablets	1 box of 2 tablets containing 1 blister of 2 tablets
1 box of 4 tablets containing 2 blisters of 2 tablets	1 box of 4 tablets containing 2 blisters of 2 tablets
1 box of 24 tablets containing 12 blisters of 2 tablets	1 box of 24 tablets containing 12 blisters of 2 tablets
	1 box of 48 tablets containing 24 blisters of 2 tablets

Not all pack sizes may be marketed.

# 15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on <a href="https://www.gov.uk">www.gov.uk</a>.

## 16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

VIRBAC 1ère avenue 2065m LID 06516 Carros France

<u>Local representatives and contact details to report suspected adverse reactions:</u>

Virbac Ltd Suffolk, IP30 9UP – UK Tel: +44 (0)-1359 243243

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

# 17. Other information

POM-V

The person administering the veterinary medicinal products to animals can self-enroll or opt-in to manage their own reminder programs by scanning the QR-code on the outer carton box with an adequate device.

Approved 14 October 2025

Gavin Hall