

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milpro 12.5 mg/125 mg film-coated tablets for dogs (AT BE BG CY CZ DE EE EL ES FR HR HU IE LT LU LV NL PL PT RO SI SK UK/NL)

Milpro Vet. 12.5 mg/125 mg film-coated tablets for dogs (DK FI IT NO SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Milbemycin oxime 12.5 mg

Praziquantel 125 mg

Excipients:

Qualitative composition of excipients and other constituents
Core:
Microcrystalline cellulose
Croscarmellose sodium
Lactose monohydrate
Starch, pregelatinised
Povidone
Magnesium stearate
Silica hydrophobic colloidal
Coat:
Natural Poultry liver flavour
Hypromellose
Microcrystalline cellulose
Macrogol stearate

Round shaped, beige to pale brown meat flavoured tablets.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

In dogs: treatment of mixed infections by adult cestodes (tapeworms) and nematodes (roundworms) of the following species:

Cestodes:

Dipylidium caninum
Taenia spp.,
Echinococcus spp.,
Mesocestoides spp.

Nematodes:

Ancylostoma caninum,
Toxocara canis,
Toxascaris leonina,
Trichuris vulpis,
Thelazia callipaeda (see specific treatment schedules under section 3.9 “Administration routes and dosage”),
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 “3.9 Administration routes and dosage”).

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

3.3 Contraindications

Do not use 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 precautions for use".

3.4 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 re-infection

3.5 Special precautions for use

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 section 3.10).

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

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.

Special precautions for the protection of the environment:

Not applicable.

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.

3.6 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 and Convulsions) Digestive tract disorder (e.g. Emesis, Diarrhoea, and Drooling)
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Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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.

3.9 Administration routes and dosage

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).

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

Weight	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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No other signs than those observed at the recommended dose have been observed (see section 3.6 “Adverse events”).

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AB51

4.2 Pharmacodynamics

Milbemycin oxime belongs to the group of macrocyclic lactones, isolated from the fermentation of *Streptomyces hygroscopicus* var. *aureolacrimosus*. It is active against mites, against larval and adult stages of nematodes as well as against larvae of *Dirofilaria immitis*. The activity of milbemycin is related to its action on invertebrate neurotransmission: milbemycin oxime, like avermectins and other milbemycins, increases nematode and insect membrane permeability to chloride ions via glutamate-gated chloride ion channels (related to vertebrate GABA_A and glycine receptors). This leads to hyperpolarisation of the neuromuscular membrane and flaccid paralysis and death of the parasite.

Praziquantel is an acylated pyrazino-isoquinoline derivative. Praziquantel is active against cestodes and trematodes. It modifies the permeability for calcium (influx of Ca²⁺) in the membranes of the parasite inducing an imbalance in the membrane structures, leading to membrane depolarisation and almost instantaneous contraction of the musculature (tetany), rapid vacuolization of the syncytial tegument and subsequent tegumental disintegration (blebbing), resulting in easier expulsion from the gastrointestinal tract or death of the parasite.

4.3 Pharmacokinetics

After oral administration of praziquantel in the dog, peak serum levels of parent are rapidly attained (T_{max} approximately 0.5-4 hours) and decline quickly (t_{1/2} approximately 1.5 hours); there is a substantial hepatic first-pass effect, with very rapid and almost complete hepatic biotransformation, principally to monohydroxylated (also some di- and tri-hydroxylated) derivatives, which are mostly glucuronide and/or sulfate conjugated before excretion. Plasma binding is about 80%. Excretion is fast and complete (about 90% in 2 days); the principal route of elimination is renal.

After oral administration of milbemycin oxime in dogs, peak plasma levels occur at about 2-4 hours, and decline with a half-life of the unmetabolised milbemycin oxime of 1-4 days. Bioavailability is about 80%.

In the rat, metabolism appears to be complete although slow, since unchanged milbemycin oxime has not been found in urine or feces. Main metabolites in the rat are monohydroxylated derivatives, attributable to hepatic biotransformation. In addition to relatively high liver concentrations, there is some concentration in fat, reflecting its lipophilicity.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Keep the blister in the outer carton.

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

5.4 Nature and composition of immediate packaging

Aluminium/ Aluminium blister pack (Oriented polyamide/Aluminium/Polyvinyl chloride sealed to Aluminium film).

Pack sizes:

Cardboard box of 2 tablets containing 1 blister of 2 tablets

Cardboard box of 4 tablets containing 2 blisters of 2 tablets

Cardboard box of 24 tablets containing 12 blisters of 2 tablets

Cardboard box of 48 tablets containing 24 blisters of 2 tablets

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription. [NL]

Veterinary medicinal product not subject to prescription. [NL]

Veterinary medicinal product subject to prescription. [AT BE BG CY CZ DE DK EE EL ES FI HR HU IE IT LT LU LV NO PL PT RO SI SK UK/NL]

Veterinary medicinal product subject to prescription except for certain pack sizes. [FR, SE]

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

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

Box with 24 blisters of 2 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milpro 12.5 mg/125 mg film-coated tablets (AT BE BG CY CZ DE EE EL ES FR HR HU IE LT LU LV NL PL PT RO SI SK UK/NL)

Milpro Vet. 12.5 mg/125 mg film-coated tablets (DK FI IT NO SE)

≥ 5 kg

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Milbemycin oxime 12.5 mg

Praziquantel 125 mg

3. PACKAGE SIZE

2 tablets

4 tablets

24 tablets

48 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

For products not subject to veterinary prescription.

In dogs: Treatment of mixed infections by adult cestodes (tapeworms) and nematodes (roundworms) of the following species:

Cestodes:

Dipylidium caninum,

Taenia spp.,

Echinococcus spp.,

Mesocestoides spp.

Nematodes:

Ancylostoma caninum,

Toxocara canis,

Toxascaris leonina,

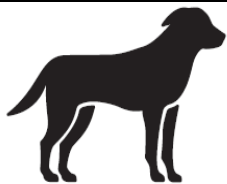
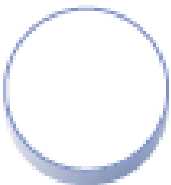
Trichuris vulpis,

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 schedules 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.

6. ROUTES OF ADMINISTRATION

Oral use

	
5 – 25 kg	x1
>25 – 50 kg	x2
>50 – 75 kg	x3

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE CONDITIONS

Keep the blister in the outer carton.

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(S)

15. BATCH NUMBER

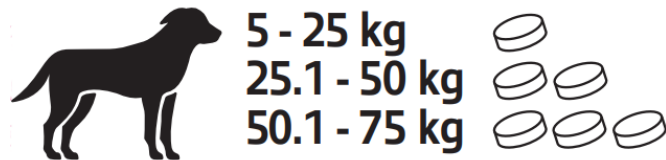
Lot {number}

MINIMUM PARTICULARS TO SMALL IMMEDIATE PACKAGING UNITS

Blister of 2 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milpro (AT BE BG CY CZ DE EE EL ES FR HR HU IE LT LU LV NL PL PT RO SI SK UK/NL)
Milpro Vet. (DK FI IT NO SE)



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

12.5 mg / 125 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. 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 (AT BE BG CY CZ DE EE EL ES FR HR HU IE LT LU LV NL PL PT RO SI SK UK/NL)

Milpro Vet. 2.5 mg/25 mg film-coated tablets for small dogs and puppies (DK FI IT NO SE)

Milpro 12.5 mg/125 mg film-coated tablets for dogs (AT BE BG CY CZ DE EE EL ES FR HR HU IE LT LU LV NL PL PT RO SI SK UK/NL)

Milpro Vet. 12.5 mg/125 mg film-coated tablets for dogs (DK FI IT NO SE)

2. Composition

Each tablet contains:

Active substances:

	Milbemycin oxime	Praziquantel	Appearance
Milpro / Mipro Vet. 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 / Milpro Vet. 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 schedules 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 / Milpro Vet. 2.5 mg/25 mg film-coated tablets for small dogs and puppies	Milpro / Mipro Vet. 12.5 mg/125 mg film-coated tablets for dogs
Do not use in puppies of less than 2 weeks of age and/or weighing less than 0.5 kg.	Do not use 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 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 re-infection.

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’).

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

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, aduclidal 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, and 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: {national system details}

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).

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

Weight	Milpro / Milpro Vet. 2.5 mg/25 mg film-coated tablets for small dogs and puppies	Milpro / Milpro Vet. 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.

9. 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 / Milpro Vet. 2.5 mg/25 mg film-coated tablets for small dogs and puppies	Milpro / Milpro Vet. 12.5 mg/125 mg film-coated tablets for dogs
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.	Keep the blister in the outer carton.

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 or household waste.

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 not subject to prescription. [NL]

Veterinary medicinal product subject to prescription. [AT BE BG CY CZ DE DK EE EL ES FI HR HU IE IT LT LU LV NO PL PT RO SI SK UK/NL]

Veterinary medicinal product subject to prescription except for certain pack sizes. [FR]

Veterinary medicinal product subject to prescription except for certain pack sizes.

[SE: Not subject to prescription:

- 2.5mg/25mg (1 box of 2 tablets and 1 box of 4 tablets);
- 12.5mg/125mg (1 box of 2 tablets and 1 box of 4 tablets)]

[SE: Subject to prescription:

- 2.5mg/25mg (1 box of 24 tablets);
- 12.5mg/125mg: (1 box of 24 tablets and 1 box of 48 tablets)]

14. Marketing authorisation numbers and pack size

Pack sizes:

Milpro / Milpro Vet. 2.5 mg/25 mg film-coated tablets for small dogs and puppies	Milpro / Milpro Vet. 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. Date on which the package leaflet was last revised

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:

VIRBAC
1^{ère} avenue 2065m LID
06516 Carros
France

Local representatives and contact details to report suspected adverse reactions:

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