

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

MILBEWORM 12.5 mg/125 mg film-coated tablets for dogs
Milbemycin oxime/Praziquantel

[Picture of dog]

Broad spectrum wormer

Dog \geq 5 kg

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Milbemycin oxime	12.5 mg
Praziquantel	125 mg

3. PHARMACEUTICAL FORM

Film coated-tablets

4. PACKAGE SIZE

2 tablets
4 tablets
24 tablets
48 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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

Crenosoma vulpis (Reduction of the level of infection),

Angiostrongylus vasorum (Reduction of the level of infection)



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

Read the package leaflet before use.



7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use

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

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the blister in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

Alfamed
13ème Rue - L.I.D.
06517 Carros Cedex
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 17902/4083

17. MANUFACTURER’S BATCH NUMBER

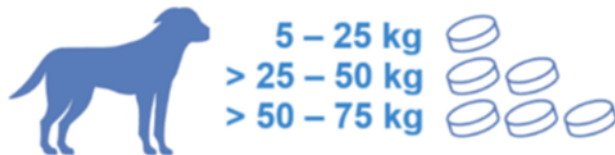
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

blister of 2 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MILBEWORM 12.5 mg/125 mg film-coated tablets for dogs \geq 5 kg
Milbemycin oxime/Praziquantel



2. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfamed

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:

Milbeworm 12.5 mg/125 mg film-coated tablets for dogs

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:

Alfamed
13ème Rue - L.I.D.
06517 Carros Cedex
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbeworm 12.5 mg/125 mg film-coated tablets for dogs
Milbemycin oxime, Praziquantel

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

Each tablet contains: Active substances:

	Appearance	Milbemycin oxime	Praziquantel
Milbeworm 12.5 mg/125 mg film-coated tablets for dogs	Round shaped, beige to pale brown meat flavoured tablets.	12.5 mg	125 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

I

Milbeworm 12.5 mg/125 mg film-coated tablets for dogs
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 other ingredients.

I See also point " SPECIAL WARNINGS".

6. ADVERSE REACTIONS

In very rare occasions, hypersensitivity reactions, systemic signs (such as lethargy), neurological signs (such as muscle tremors and ataxia) and/or gastrointestinal signs (such as emesis, diarrhoea, anorexia and drooling) may be observed in dogs after administration of the veterinary medicinal product.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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:

II

Weight	Milbeworm 12.5 mg/125 mg film-coated tablets for dogs
0.5 - 1 kg	
> 1 – 5 kg	
> 5 – 10 kg	
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.

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 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 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 product can replace the monovalent product containing milbemycin oxime alone.

10. **WITHDRAWAL PERIOD**

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.

Milbepworm 12.5 mg/125 mg film-coated tablets for dogs

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 WARNINGS**

Special warnings for use in animals:

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.

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.

III Clinical signs in Collies are similar to those seen in the general dog population when overdosed (see also section 'Overdose').

As per good veterinary practice, animals should be weighed to ensure accurate dosing.

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 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 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 product.

No studies have been performed with severely debilitated dogs or individuals with seriously compromised 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, tapeworm infection is unusual. Treatment of animals less than 4 weeks old with a combination product may therefore not be necessary.

User safety – Please read before every use:

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.

Other precautions:

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) If the dog has visited areas where *Echinococcus* spp. are prevalent, a veterinarian should be consulted.

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 product has not been performed, use during pregnancy and lactation only according to a benefit/risk assessment by the responsible veterinarian. Also no such studies have been performed with reproducing animals.

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 product and other macrocyclic lactones.

Overdose (symptoms, emergency procedures, antidotes):

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

December 2021

15. OTHER INFORMATION

Available pack sizes:

Milbepworm 12.5 mg/125 mg film-coated tablets for dogs
1 box of 2 tablets containing 1 blister of 2 tablets (divisible per tablet)
1 box of 4 tablets containing 2 blisters of 2 tablets (divisible per tablet)
1 box of 24 tablets containing 12 blisters of 2 tablets (divisible per tablet)
1 box of 48 tablets containing 24 blisters of 2 tablets (divisible per tablet)

Not all pack sizes may be marketed.

Approved 10 December 2021

