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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Milbemycin oxime, Praziquantel

[Picture of dog]

Broad spectrum wormer

Dog ≥ 5 kg

2. STATEMENT OF ACTIVE AND OTHER 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

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 (see specific treatment schedules under section 4.9 "Amounts to be administered and administration route").
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 WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet.

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

Disposal: 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

[QR code]

16. MARKETING AUTHORISATION NUMBER(S)

Vm17902/4063

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

blister of 2 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pramilon 12.5 mg/125 mg film-coated tablets for dogs ≥ 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.
[refer to the picto section 1]

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Pramilon 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

Pramilon (UK) / Milbetel (FR) / No Worm Pro (NL) 2.5 mg/25 mg film-coated tablets for small dogs and puppies
Pramilon (UK) / Milbetel (FR) / No Worm Pro (NL) 12.5 mg/125 mg film-coated tablets for dogs
Milbemycin oxime, Praziquantel

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

Each tablet contains: Active substances:

	Appearance	Milbemycin oxime	Praziquantel
Pramilon 12.5 mg/125 mg film-coated tablets for dogs	Round shaped, beige to pale brown meat flavoured tablets.	12.5 mg	125.0 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 4.9 "Amounts to be administered and administration route").
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

Pramilon 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.
See also point "SPECIAL WARNINGS".

6. ADVERSE REACTIONS

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

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.

Animals should be weighed to ensure accurate dosing.
The product should be administered with or after some food.
The tablets are meat flavoured and easy to administer tablets (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	**Pramilon (UK) / Milbetel (FR) / No Worm Pro (NL) 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.

Pramilon 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 WARNING(S)

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.

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 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 (see also section 4.10).

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.

Echinococcosis 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. If the dog has visited areas where *Echinococcus* spp. is prevalent a veterinarian should be consulted

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.

As the tablets are flavoured, they should be stored in a safe place out of the reach of animals.

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.

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.

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.

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. Also no such studies have been performed with reproducing animals.

Overdose (symptoms, emergency procedures, antidotes):
No other signs than those observed at the recommended dose have been observed (see section “ADVERSE REACTIONS”) but more pronounced.

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

April 2021

15. OTHER INFORMATION

Available pack sizes:

1 box of 2 tablets containing 1 blister of 2 tablets
1 box of 4 tablets containing 2 blisters of 2 tablets

Not all pack sizes may be marketed.

Approved: 23/09/21