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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MILBEWORM 4 mg/10 mg film-coated tablets for small cats and kittens
Milbemycin oxime/Praziquantel

[Picture of small Cat/kitten]

Broad spectrum wormer

Cat 0.5 – 2 kg

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Milbemycin oxime	4 mg
Praziquantel	10 mg

3. PHARMACEUTICAL FORM

Film-coated tablets

4. PACKAGE SIZE

2 tablets
4 tablets
24 tablets

5. TARGET SPECIES

Small cats and kittens

6. INDICATION(S)

In cats: treatment of mixed infections by immature and adult cestodes (tapeworms) and adult nematodes (roundworms) of the following species:
Cestodes:
Echinococcus multilocularis,
Dipylidium caninum,
Taenia spp.,
Nematodes:
Ancylostoma tubaeforme,
Toxocara cati
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 route

	
0.5 - 1 kg	x1/2
> 1 – 2 kg	x1

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

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 17902/4080

17. MANUFACTURER'S BATCH NUMBER

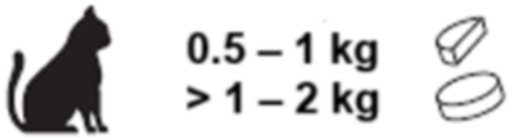
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

blister of 2 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MILBEWORM 4 mg/10 mg film-coated tablets for small cats and kittens 0.5 – 2 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 4 mg/10 mg film-coated tablets for small cats and kittens

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 film-coated tablets for small cats and kittens
Milbemycin oxime, Praziquantel

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

Each tablet contains: Active substances:

	Appearance	Milbemycin oxime	Praziquantel
Milbeworm 4 mg/10 mg film-coated tablets for small cats and kittens	Oval shaped, dark brown, meat flavoured tablets with a score on both sides.	4 mg	10 mg

The tablets can be divided into halves.

4. INDICATION(S)

In cats: treatment of mixed infections by immature and adult cestodes (tapeworms) and adult nematodes (roundworms) of the following species:
Tapeworms (cestodes):
Echinococcus multilocularis,
Dipylidium caninum,
Taenia spp.,
Roundworms (nematodes):
Ancylostoma tubaeforme,
Toxocara cati
The product can also be used in the Prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes is indicated.

5. CONTRAINDICATIONS

Milbeworm 4 mg/10 mg film-coated tablets for small cats and kittens
Do not use in kittens of less than 6 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 point "SPECIAL WARNINGS".

6. ADVERSE REACTIONS

In very rare occasions, especially in young cats, hypersensitivity reactions, systemic signs (such as lethargy), neurological signs (such as ataxia and muscle tremors) and/or gastrointestinal signs (such as emesis and diarrhoea) may be observed 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

Cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

Oral route.
Minimum recommended dose rate: 2 mg of milbemycin oxime and 5 mg of praziquantel per kg are given orally as a single dose.

The product should be administered with or after some food.
The product is a small size tablet.
To aid with administration, the product has been coated with a meat flavour.

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

Weight	**Milbeworm 4 mg/10 mg film-coated tablets for small cats and kittens**
0.5 - 1 kg	1/2 tablet
> 1 – 2 kg	1 tablet
2 – 4 kg	
>4 – 8 kg	
>8 – 12 kg	

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 monthly prevention of heartworm disease.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

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

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.

Shelf life after first opening the immediate packaging: 6 months.

Keep the blister in the outer carton.

12. SPECIAL WARNINGS

Special warnings for each target species:

It is recommended to treat all the animals living in the same household concomitantly.

In order to develop an effective worm control programme local epidemiological information and the living conditions of the cat 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.

When *D. 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:

No studies have been performed with severely debilitated cats 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.

Studies have shown that 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 the absence of data on cats with microfilaraemia, its use should be according to a benefit risk assessment by the attending veterinarian.

As per good veterinary practice, animals should be weighed to ensure accurate dosing.
Ensure cats and kittens weighing between 0.5 kg and ≤2 kg receive the appropriate tablet strength (4 mg MBO/10 mg praziquantel) and the appropriate dose (1/2 or 1 tablet) for the corresponding weight band (1/2 tablet for cats weighing 0.5 to 1 kg; 1 tablet for cats weighing >1 to 2 kg – 1 tablet).

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

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 cat 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 queens, 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):

In a study conducted with the product administered at 1X, 3X and 5X the therapeutic dose, and for a duration which exceed the therapeutic indication, *i.e.* 3 times at 15 day-intervals, signs uncommonly reported at the recommended dose (see section ‘ADVERSE REACTIONS’) have been observed at 5-fold the therapeutic dose after

the second and third treatments. These signs disappeared spontaneously within a day.

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:

Milpro 4 mg/10 mg film-coated tablets for small cats and kittens
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)

Not all pack sizes may be marketed.

Approved 10 December 2021