

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemycin oxime Praziquantel Chew Alfamed 2.5 mg / 25.0 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substances:

Milbemycin oxime 2.5 mg
Praziquantel 25.0 mg

3. PACKAGE SIZE

2 chewable tablets
4 chewable tablets
24 chewable tablets

4. TARGET SPECIES

Dog

5. INDICATIONS

For products not subject to veterinary prescription.
Treatment of mixed infections by adult cestodes and nematodes of the following species:

- Cestodes:

Dipylidium caninum

Taenia spp.

Echinococcus spp.

Mesocestoides spp.

- Nematodes:

Ancylostoma caninum

Toxocara canis

Toxascaris leonina

Trichuris vulpis

Crenosoma vulpis

Angiostrongylus vasorum (Reduction of the level of infection by immature adult (L5) and adult parasite stages)

Thelazia callipaeda

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.
1 tablet for dogs of 1 – 5 kg.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in the original package to protect from light.

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

ALFAMED

14. MARKETING AUTHORISATION NUMBERS

Vm 17902/3000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemycin oxime Praziquantel Chew Alfamed



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Milbemycin oxime 2.5 mg / Praziquantel 25.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Milbemycin oxime Praziquantel Chew Alfamed 2.5 mg / 25.0 mg chewable tablets for small dogs and puppies

2. Composition

Each tablet contains:

Active substances:

Milbemycin oxime 2.5 mg
Praziquantel 25.0 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Macrogols 3350	32.90 mg
Soya-bean oil, refined	26.32 mg
Ferric oxide (E172)	0.66 mg
Butylhydroxyanisole (E320)	0.26 mg

Brown to dark brown rounded rectangular chewable tablet.

3. Target species

Dog (small dogs and puppies weighing at least 1 kg).

4. Indications for use

Treatment of mixed infections by adult cestodes and nematodes of the following species:

- Cestodes:

Dipylidium caninum

Taenia spp.

Echinococcus spp.

Mesocestoides spp.

- Nematodes:

Ancylostoma caninum

Toxocara canis

Toxascaris leonina

Trichuris vulpis

Crenosoma vulpis

Angiostrongylus vasorum (Reduction of the level of infection by immature adult (L5) and adult parasite stages; see specific treatment and prevention disease schedules under section “Dosage of each species, routes and method of administration”).

Thelazia callipaeda (see specific treatment schedule under section “Dosage of each species, routes and method of 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

Do not use in dogs weighing less than 1 kg.

Do not use in cases of hypersensitivity to the active substances, or to any of the excipient(s).

6. Special warnings

Special warnings:

The possibility that other animals in the same household can be a source of re-infection with cestodes and nematodes should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.

The use of the veterinary medicinal product should follow the implementation of appropriate diagnostic measures towards mixed infections by nematodes and cestodes with consideration of animal history and characteristics (e.g. age, health status), environment (e.g. kennelled dogs, hunting dogs), feeding (e.g. access to raw meat), geographical location and travel. Judgement of the administration of the veterinary medicinal product in dogs at risk from mixed re-infections or in specific at risk situations (such as zoonotic risks), should be made by the veterinarian responsible.

Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

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

When infection with the cestode *D. caninum* has been confirmed, concomitant treatment against intermediate hosts, such as fleas and lice, should be discussed with a veterinarian to prevent re-infection.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

In third countries (USA), resistance of *Dipylidium caninum* to praziquantel as well as cases of multiple-drug resistance of *Ancylostoma caninum* and resistance of *Dirofilaria immitis* to macrocyclic lactones have already been reported.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

In the absence of risk of co-infection with the indicated parasites, a narrow spectrum veterinary medicinal product should be used, when available.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method. Confirmed resistance should be reported to the marketing holder or to the competent authority.

Special precautions for safe use in the target species:

Studies with milbemycin oxime indicate that the margin of safety in MDR1 mutant (-/-) dogs of Collie or related breeds is lower than in other breeds. In these dogs, the minimum recommended dose should be strictly observed (See section "Dosage for each species, routes and method of administration").

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 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 if 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 a benefit/risk assessment by the responsible veterinarian.

In dogs less than 4 weeks old, tape worm infection is unusual. Treatment of animals less than 4 weeks old with a combination veterinary medicinal 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:

This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to butylhydroxyanisole, macrogols or soya (bean) oil should avoid contact with the veterinary medicinal product. If contact occurs, wash hands and seek medical advice in case of hypersensitivity reactions.

This veterinary medicinal product may be harmful after accidental ingestion. To avoid accidental ingestion, particularly by a child, blister cards should be inserted back into the carton and kept out of sight and reach of children.

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.

Wash hands after use.

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 (e.g., experts or institutes of parasitology).

Pregnancy:

Can be used during pregnancy.

Lactation:

Can be used during lactation.

Fertility:

Can be used in breeding 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 veterinary medicinal product and other macrocyclic lactones. Also no such studies have been performed with reproducing animals.

Overdose:

The adverse reactions observed are the same as those observed at the recommended dose (see section "Adverse events") but more pronounced.

7. Adverse events

Dog:

<p>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</p>	<p>Hypersensitivity reaction Systemic disorders (e.g. lethargy, anorexia) Neurological disorders (e.g. ataxia, convulsion, muscle tremor) Digestive tract disorders (e.g. emesis, drooling, diarrhoea)</p>
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Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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. The veterinary medicinal product should be administered with or after some food.

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

Weight	Number of Tablet
1 – 5 kg	1 tablet
>5 - 10 kg	2 tablets

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under dosing.

Underdosing could result in ineffective use and may favour resistance development. The need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product containing milbemycin oxime alone.

9. Advice on correct administration

The veterinary medicinal product is given once by oral administration with or after some food.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in the original package to protect from light.

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

The veterinary medicinal product should not enter water courses as milbemycin oxime 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

Aluminum/aluminum blister (OPA/Alu/PVC, sealed with Alu/Paper film) in cardboard box.

Available pack sizes:

1 box with 1 blister, each blister contains 2 chewable tablets

1 box with 2 blisters, each blister contains 2 chewable tablets

1 box with 12 blisters, each blister contains 2 chewable tablets

Vm 17902/3000

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 www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Alfamed
13ème rue – L.I.D
Carros Cedex
06517
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.

To be completed during national phase.

17. Other information

Approved: 12 June 2024

Gavin Hall