PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemycin oxime Praziquantel Alfamed 2.5 mg / 25.0 mg chewable tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each chewable tablet contains:

Active substances:
Milbemycin oxime 2.5 mg
Praziquantel 25.0 mg

Excipients:

Macrogol 3350 (E1520) 32.90 mg,

Ferric oxide (E172) 0.66 mg,

Butylhydroxyanisole (E320) 0.26 mg,

Soya-bean oil, refined 26.32 mg

3. PACKAGE SIZE

2 chewable tablets
4 chewable tablets
24 chewable tablets

4. TARGET SPECIES

Small dogs and puppies

1 tablet for dogs of 1 - 5 kg

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 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 the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

ALFAMED

14. MARKETING AUTHORISATION NUMBER

Vm 17902/5000

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V (‘Veterinary medicinal product subject to prescription’)

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {ALUMINIUM BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemycin oxime Praziquantel Alfamed

5-25 kg

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Milbemycin oxime 2.5 mg / Praziquantel 25.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each chewable tablet contains:

Active substances:
Milbemycin oxime 2.5 mg
Praziquantel 25.0 mg

Excipients:

Macrogol 3350 (E1520) 32.90 mg,
Ferric oxide (E172) 0.66 mg,
Butylhydroxyanisole (E320) 0.26 mg,
Soya-bean oil, refined 26.32 mg

Brown to dark brown rounded rectangular chewable tablet.

3. TARGET SPECIES

Dog

4. INDICATIONS FOR USE

In dogs: 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*
In *Angiostrongylus vasorum,* the product is indicated for the reduction of the level of infection by immature adult (L5) and adult parasite stages (see specific treatment and prevention disease schedules under section “Dosage for each species, route(s) and method of administration”).
Thelazia callipaeda: please refer to specific treatment schedule under section “Dosage for each species, route(s) and method of administration”.

The 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 excipients.

6. SPECIAL WARNING(S)

Special warnings for each target species:

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

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

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, 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 and lactation:

The safety of the veterinary medicinal product has been established during pregnancy and lactation.
Can be used in pregnant and lactating bitches.
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 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

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction Systemic disorders (such as lethargy and anorexia) Neurological disorders (such as ataxia, convulsion and muscle tremor) Digestive tract disorders (such as emesis, drooling and diarrhoea)

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 its local representative using the contact details at the end of this leaflet, or via your national reporting system.

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

Milbemycin oxime Praziquantel Alfamed is administered at a minimum recommended dose rate of 0.5 mg of milbemycin oxime and 5 mg of praziquantel per kg body weight. The 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 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 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.

9. ADVICE ON CORRECT ADMINISTRATION

Milbemycin oxime Praziquantel Alfamed is given once by oral administration with or after some food.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.

Store below 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 blister and 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.

The veterinary medicinal product should not enter water courses as it may be dangerous for fish and other aquatic organisms.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

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

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

Vm 17902/5000

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 authorization holder and manufacturer responsible for batch release:

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

Local representative and contact details to report suspected adverse reactions:

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

17. OTHER INFORMATION

POM-V ('Veterinary medicinal product subject to prescription')

For animal treatment only.

Approved: 12 June 2024

Gavin Hall