MILBEWORM

2.5 MG / 25 MG FILM-COATED TABLETS FOR SMALL DOGS AND PUPPIES

12.5 MG / 125 MG FILM-COATED TABLETS FOR DOGS

MILBEMYCIN OXIME, PRAZIQUANTEL

Marketing authorisation holder and manufacturer responsible for batch release:
ALFAMED - 13ème Rue - L.I.D. - 06517 Carros
cedex - FRANCE

STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)
Each tablet contains: Active substances:

	Appearance	Milbemycin oxime	Praziquantel
Milbeworm 2.5 mg/25 mg film-coated tablets for small dogs and puppies	Oval-shaped, beige to pale brown, meat flavoured tablets with a score on both sides. The tablets can be divided into halves.	2.5 mg	25.0 mg
Milbeworm 12.5 mg/125 mg film-coated tablets for dogs	Round-shaped, beige to pale brown meat-f lavoured tablets.	12.5 mg	125.0 mg

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, Trichuris vulpis, 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.

CONTRAINDICATIONS
Milbeworm 2.5 mg/25 mg film-coated tablets for small dogs and puppies
- Do not use in puppies of less than 2 weeks of age and/or weighing less than 0.5 kg

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. See also 'SPECIAL WARNINGS'.

ADVERSE REACTIONS
In very rare occasions, 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.

TARGET SPECIES
Dogs.

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:

Weight	Milbeworm 2.5 mg/25 mg film-coated tablets for small dogs and puppies	Milbeworm 12.5 mg/125 mg film-coated tablets for dogs
0.5 - 1 kg	1/2 tablet	
> 1 – 5 kg	1 tablet	
> 5 – 10 kg	2 tablets	
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.

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.

WITHDRAWAL PERIOD:
Not applicable.

SPECIAL STORAGE PRECAUTIONS:
Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.

Milbeworm 2.5 mg/25 mg film-coated tablets for small dogs and puppies	Milbeworm 12.5 mg/125 mg film-coated tablets for dogs
Keep the blister in the outer carton. Half tablets should be stored in the original blister and be used for the next administration. Shelf life after first opening the immediate packaging: 6 months.	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.

SPECIAL WARNINGS
Special warnings for use in each target species: 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. Clinical signs in Collies are similar to those seen in the general dog population when overdosed.
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 vet.
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.
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 vet. 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').

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.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED
August 2014

OTHER INFORMATION
Available pack sizes:

Milbeworm 2.5 mg/25 mg film-coated tablets for small dogs and puppies	Milbeworm 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 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 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 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.

FOR ANIMAL TREATMENT ONLY

To be supplied only on veterinary prescription.

Milbeworm 2.5 mg / 25 mg film-coated tablets for small dogs and puppies

UK only

POM-V Vm 17902/4082

Local representative: MiGroup, CVS House, Owen Road, Diss, IP22 4ER

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

UK only

POM-V Vm 17902/4083

Local representative: MiGroup, CVS House, Owen Road, Diss, IP22 4ER