

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

VetUK dog Wormer 12.5 mg/125 mg film-coated tablets

≥ 5 kg

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Milbemycin oxime	12.5 mg
Praziquantel	125 mg

3. PACKAGE SIZE

2 tablets
4 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

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:


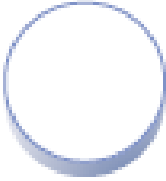
Ancylostoma caninum,
Toxocara canis,
Toxascaris leonina,
Trichuris vulpis,
Thelazia callipaeda (see specific treatment schedules under section "Advice on correct administration").
Crenosoma vulpis (reduction of the level of infection),

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.

6. ROUTES OF ADMINISTRATION

Oral use

	
5 – 25 kg	x1
>25 – 50 kg	x2
>50 – 75 kg	x3

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE CONDITIONS

Keep the blister in the outer carton.

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 17902/3003

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister of 2 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VetUK dog Wormer



≥ 5 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

12.5 mg / 125 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

VetUK Dog Wormer 2.5 mg/25 mg Film-coated Tablets for Small Dogs and Puppies
VetUK Dog Wormer 12.5 mg/125 mg Film-coated Tablets for Dogs

2. Composition

Each tablet contains:

Active substances:

	Milbemycin oxime	Praziquantel	Appearance
VetUK Dog Wormer 2.5 mg/25 mg Film-coated Tablets for Small Dogs and Puppies	2.5 mg	25.0 mg	Oval shaped, beige to pale brown, meat flavoured tablets with a score on both sides. The tablets can be divided into halves.
VetUK Dog Wormer 12.5 mg/125 mg Film-coated Tablets for Dogs	12.5 mg	125.0 mg	Round shaped, beige to pale brown meat flavoured tablets.

3. Target species

Dogs.

4. Indications for use

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 "Advice on correct administration"),

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 veterinary medicinal product can also be used in the prevention of heartworm disease (*Dirofilaria immitis*), if concomitant treatment against cestodes is indicated.

5. Contraindications

VetUK Dog Wormer 2.5 mg/25 mg Film-coated Tablets for Small Dogs and Puppies	VetUK Dog Wormer 12.5 mg/125 mg Film-coated Tablets for Dogs
Do not use in puppies of less than 2 weeks of age and/or weighing less than 0.5 kg.	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 excipients.

See also section "Special warnings".

6. Special warnings

Special warnings:

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 safe use in the target species:

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 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 also sub-section “Overdose”).

As per good veterinary practices, 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 veterinary medicinal 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 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 the 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.

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:

Wash hands after use.

Part tablets should be returned to the open blister and inserted into the outer carton. In case accidental ingestion of the tablets, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

Pregnancy and lactation:

In a field study, the safety of the combination of both active substances was established in breeding bitches, including during pregnancy and lactation.

In these particular circumstances, use only according to the 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 veterinary medicinal product and other macrocyclic lactones. Also no such studies have been performed with reproducing animals.

Overdose:

No other signs than those observed at the recommended dose have been observed (see section “Adverse events”) but more pronounced.

7. Adverse events

Dogs:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reaction
Systemic disorder (e.g. Lethargy and Anorexia)
Neurological disorder (e.g. Muscle tremors, Ataxia (incoordination) and Convulsions)
Digestive tract disorder (e.g. Emesis (vomiting), Diarrhoea, and Drooling)

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: E-mail: adverse.events@vmd.gov.uk
Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

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 orally.

The veterinary medicinal 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	VetUK Dog Wormer 2.5 mg/25 mg Film-coated Tablets for Small Dogs and Puppies	VetUK Dog Wormer 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 veterinary medicinal 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 veterinary medicinal product and continue with the monovalent 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 product containing milbemycin oxime alone.

10. Withdrawal periods

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.

VetUK Dog Wormer 2.5 mg/25 mg Film-coated Tablets for Small Dogs and Puppies	VetUK Dog Wormer 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 (for half tablets): 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.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as this 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

Vm 17902/3004

Vm 17902/3003

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.

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 and contact details to report suspected adverse reactions:

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

Gavin Hall
Approved: 07 April 2025