# PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alpramil 12.5 mg/125 mg tablets

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains: milbemycin oxime 12.5 mg and praziquantel 125.0 mg.

## 3. PACKAGE SIZE

1 tablet
2 tablets
4 tablets
10 tablets
20 tablets
25 tablets
40 tablets
50 tablets
100 tablets

## 4. TARGET SPECIES

Dogs weighing at least 5 kg.

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Oral use.

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp. {mm/yyyy}

## 9. SPECIAL STORAGE PRECAUTIONS

## 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

Alfasan Nederland B.V.

## 14. MARKETING AUTHORISATION NUMBERS

Vm 36408/5005
Vm 36408/3005

## 15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {ALUMINIUM BLISTER}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alpramil

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

12.5 mg milbemycin oxime/125 mg praziquantel/tablet

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Alpramil 5 mg/50 mg tablets for dogs weighing at least 0.5 kg
Alpramil 12.5 mg/125 mg tablets for dogs weighing at least 5 kg
Alpramil 20 mg/200 mg tablets for dogs weighing at least 8 kg

### 2. Composition

Each 5 mg/50 mg tablet contains:

**Active substances:**

| | |
|---|---|
| Milbemycin oxime | 5.0 mg |
| Praziquantel | 50.0 mg |

Light brown with brown spots, round and convex 11 mm tablet with a cross-shaped break line on one side. Tablets can be divided into halves and quarters.

Each 12.5 mg/125 mg tablet contains:

**Active substances:**

| | |
|---|---|
| Milbemycin oxime | 12.5 mg |
| Praziquantel | 125.0 mg |

Light brown with brown spots, round and convex 15 mm tablet.

Each 20 mg/200 mg tablet contains:

**Active substances:**

| | |
|---|---|
| Milbemycin oxime | 20.0 mg |
| Praziquantel | 200.0 mg |

Light brown with brown spots, round and convex 18 mm tablet.

## 3. Target species

5 mg/50 mg tablet: Dogs weighing at least 0.5 kg.
12.5 mg/125 mg tablet: Dogs weighing at least 5 kg.
20 mg/200 mg tablet: Dogs weighing at least 8 kg.

## 4. Indications for use

Treatment of mixed infections by adult cestodes and nematodes of the following species susceptible to praziquantel and milbemycin oxime:

- Cestodes:
*Dipylidium caninum*
*Taenia* spp.
*Echinococcus* spp.
*Mesocestoides* spp.

- Nematodes :
*Ancylostoma caninum*
*Toxocara canis*
*Toxascaris leonina*
*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 “Dosage for each species, routes and method of administration”)
*Thelazia callipaeda* (see specific treatment schedule under “Dosage for 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

5 mg/50 mg tablet: Do not use in dogs weighing less than 0.5 kg.
12.5 mg/125 mg tablet: Do not use in dogs weighing less than 5 kg.
20 mg/200 mg tablet: Do not use in dogs weighing less than 8 kg.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
See also section on Special warnings (Special precautions for safe use in the target species).

## 6. Special warnings

Special warnings:
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.
In order to develop an effective worm control programme local epidemiological information and the risk of exposure of the dog should be taken into account, and it is recommended to seek professional advice.
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. Unnecessary use of antiparasitics or use deviating from the instructions may increase the resistance selection pressure and lead to reduced efficacy. In third countries (USA), resistance of *Dipylidium caninum* to praziquantel as well as cases of multiple-drug resistance of *Ancylostoma caninum* to milbemycin oxime have already been reported.

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 compared to the normal population. 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 these dogs are similar to those seen in the general dog population (see Adverse events).

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 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 veterinary medicinal product may therefore not be necessary.

As the tablets are flavoured, they should be stored in a safe place out of the reach of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may be harmful when ingested, particularly by children.
Avoid accidental ingestion.
Any unused tablet parts of 5 mg/50 mg tablets should be discarded or returned to the open blister, inserted back into the outer packaging and used at the next administration. The veterinary medicinal product should be stored in a safe place.
In case of accidental ingestion, 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 of 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:
Can be used during pregnancy and lactation.

Fertility:
Can be used in breeding animals.

Interaction with other medicinal products and other forms of interaction:
The concurrent use of the veterinary medicinal product with selamectin is well tolerated. No interactions were observed when the recommended dose of the macrocyclic lactone selamectin was administered during treatment with the veterinary medicinal product 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 Adverse events).

## 7. Adverse events

Dogs:

| | |
|---|---|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Hypersensitivity reaction;<br>Systemic disorders (e.g. lethargy, anorexia);<br>Neurological disorders (e.g. muscle tremor and ataxia (incoordination));<br>Digestive tract disorders (e.g. emesis (vomiting), diarrhoea and drooling). |

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 at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

## 8. Dosage for each species, routes and method of administration

Oral use.
To ensure a correct dosage, body weight should be determined as accurately as possible.
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.

Depending on the bodyweight of the dog and the availability of tablet strengths, practical dosing examples are as follows:

5 mg/50 mg tablet:

| **Weight (kg)** | **5 mg/50 mg tablet** | |
|---|---|---|
| **0.5 – 2.5** | | ¼ tablet |
| **> 2.5 – 5** | | ½ tablet |
| **> 5 – 10** | | 1 tablet |
| **> 10 – 15** | | 1½ tablets |

12.5 mg/125 mg tablet:

| Weight (kg) | 12.5 mg/125 mg tablet | |
|---|---|---|
| **> 5 – 25** | ◯ | 1 tablet |
| **> 25 – 50** | ◯◯ | 2 tablets |

20 mg/200 mg tablet:

| Weight (kg) | 20 mg/200 mg tablet | |
|---|---|---|
| **> 8 – 40** | ◯ | 1 tablet |
| **> 40 – 80** | ◯◯ | 2 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 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.

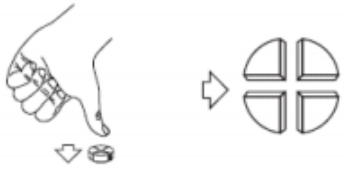
In endemic areas administration of the veterinary medicinal product every four weeks will prevent angiostrongylosis by reducing immature adult (L5) and adult parasite burden, where concomitant treatment against cestodes is indicated.

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 5 mg/50 mg tablets can be divided into halves and quarters to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.
Halves: press down with your thumbs on both sides of the tablet:

Quarters: press down with your thumb in the middle of the tablet:



## 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 storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after Exp. The expiry date refers to the last day of that month.
5 mg/50 mg tablet: Shelf life of divided tablets after first opening of the immediate packaging: 7 days.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
This 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

Vm 36408/5005
Vm 36408/3005

Vm 36408/5004
Vm 36408/3004

Vm 36408/5006
Vm 36408/3006

OPA/Aluminium/PVC-Aluminium blister containing 1, 2 or 4 tablets.

Box with 1 blister containing 1 tablet.
Box with 1 blister containing 2 tablets.
Box with 1 blister containing 4 tablets.
Box with 10 blisters each containing 1 tablet.
Box with 10 blisters each containing 2 tablets.
Box with 10 blisters each containing 4 tablets.
Box with 25 blisters each containing 1 tablet.
Box with 25 blisters each containing 2 tablets.
Box with 25 blisters each containing 4 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:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Manufacturer responsible for batch release:
LelyPharma B.V.
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

Local representatives and contact details to report suspected adverse reactions:
DUGV (UK) Ltd. Union House,
111 New Union Street,
Coventry, CV1 2NT
uksales@dugganvet.com

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

## 17. Other information

POM-V

Approved 28 October 2025

Gavin Hall