

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MILBETAB 2.5 mg/25 mg tablets for small dogs and puppies  
MILBETAB, 2.5 mg/25 mg tablets for small dogs and puppies (EE)  
MILIPRAZ 2.5 mg/25 mg tablets for small dogs and puppies (NO)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

### Active substances:

Milbemycin oxime 2.5 mg  
Praziquantel 25.0 mg

### Excipients:

Qualitative composition of excipients and other constituents
Lactose Monohydrate
Croscarmellose Sodium
Grilled Meat Flavour
Yeast Extract
Povidone K30
Cellulose, Microcrystalline
Silica, Colloidal Anhydrous
Talc
Magnesium Stearate

A white to off white oval shaped tablet with a breakline on both sides. The tablet can be divided into halves.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs (1–5 kg).

### 3.2 Indications for use for each target species

For dogs with, or at risk from mixed infections by cestodes, gastro-intestinal nematodes, eyeworm, lungworms and/or heartworm. This veterinary medicinal product is only indicated when use against cestodes and nematodes or prevention of heartworm disease/angiostrongylosis is indicated at the same time.

#### Cestodes:

Treatment of tapeworms: *Dipylidium caninum*, *Taenia* spp., *Echinococcus* spp., *Mesocestoides* spp.

#### Gastrointestinal Nematodes:

Treatment of:

Hookworm: *Ancylostoma caninum*,

Roundworms: *Toxocara canis*, *Toxascaris leonina*

Whipworm: *Trichuris vulpis*

#### Eyeworm

Treatment of *Thelazia callipaeda* (see specific treatment schedule under section 3.9 “Administration routes and dosage”).

### Lungworms

Treatment of:

*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 3.9

“Administration routes and dosage”),

*Crenosoma vulpis* (Reduction of the level of infection).

### Heartworm

Prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes is indicated.

## **3.3 Contraindications**

Do not use in puppies of less than 2 weeks of age and/or weighing less than 0.5 kg.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

See also section 3.5 "Special precautions for use".

## **3.4 Special warnings**

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC 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.

In the absence of risk of co-infection with nematodes or cestodes, a narrow spectrum veterinary medicinal product should be used.

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

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

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

Resistance of *Dipylidium caninum* to praziquantel as well as cases of multi-drug resistance of *Ancylostoma caninum* to milbemycin oxime and resistance of *Dirofilaria immitis* to macrocyclic lactones have been reported in dogs.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method.

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

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

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

## **3.5 Special precautions for use**

### Special precautions for safe use in the target species:

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.

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 section 3.10 “Symptoms of overdose”).

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:

The product may be harmful in case of ingestion, especially by a child.

To avoid accidental ingestion, the product should be stored out of sight and reach of children.

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.

Unused part tablets should be discarded

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

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).

### 3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (such as Diarrhoea, Drooling, Emesis) Hypersensitivity reaction Neurological disorders (such as Ataxia, Convulsions, Muscle tremors) Systemic disorders (such as Anorexia, Lethargy)
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Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing

authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

#### Pregnancy and lactation:

Can be used during pregnancy and lactation.

#### Fertility:

Can be used in breeding animals.

### 3.8 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 with other macrocyclic lactones. Also, no such studies have been performed with breeding animals.

### 3.9 Administration routes and dosage

Oral use.

Minimum recommended dose rate 0.5 mg milbemycin oxime and 5 mg praziquantel per kg are given as a single dose.

The veterinary medicinal product should be administered with or after some food.

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

Underdosing could result in ineffective use and may favour resistance development.

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

Weight	Number of Tablet
0.5 - 1 kg	½ tablet
> 1 – 5 kg	1 tablet
> 5 – 10 kg	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 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 veterinary medicinal 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 veterinary medicinal product can replace the monovalent product containing milbemycin oxime alone.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No other signs than those observed at the recommended dose have been observed.

The tolerance of the veterinary medicinal product in young puppies from these breeds has not been investigated.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

### **3.12 Withdrawal periods**

Not applicable.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code: QP54A B51**

### **4.2 Pharmacodynamics**

Milbemycin oxime belongs to the group of macrocyclic lactones, isolated from the fermentation of *Streptomyces hygroscopicus* var. *aureolacrimosus*. It is active against mites, against larval and adult stages of nematodes as well as against larvae of *Dirofilaria immitis*.

The activity of milbemycin is related to its action on invertebrate neurotransmission: Milbemycin oxime, like avermectins and other milbemycins, increases nematode and insect membrane permeability to chloride ions via glutamate-gated chloride ion channels (related to vertebrate GABAA and glycine receptors). This leads to hyperpolarisation of the neuromuscular membrane and flaccid paralysis and death of the parasite.

Praziquantel is an acylated pyrazino-isoquinoline derivative. Praziquantel is active against cestodes and trematodes. It modifies the permeability for calcium (influx of Ca<sup>2+</sup>) in the membranes of the parasite inducing an imbalance in the membrane structures, leading to membrane depolarisation and almost instantaneous contraction of the musculature (tetany), rapid vacuolization of the syncytial tegument and subsequent tegumental disintegration (blebbing), resulting in easier expulsion from the gastrointestinal tract or death of the parasite.

Avermectins and milbemycin have similar molecular targets - glutamate-gated chloride channels. These channels have multiple isoforms in nematodes which may have different susceptibilities to avermectins/milbemycin. Different mechanisms of avermectins and milbemycin resistance may be due to the multiplicity of glutamate-gated chloride channels subtypes. The resistance mechanism for praziquantel is still unknown.

### **4.3 Pharmacokinetics**

After oral administration of praziquantel in the dog, peak serum levels of parent are rapidly attained (T<sub>max</sub> approximately **0.5-12** hours) and decline quickly (t<sub>1/2</sub> approximately **2** hours). There is a substantial hepatic first-pass effect, with very rapid and almost complete hepatic biotransformation, principally to monohydroxylated (also some di- and tri-hydroxylated) derivatives, which are mostly glucuronide and/or sulfate conjugated before excretion. Plasma binding is about 80%. Excretion is fast and complete (about 90% in 2 days); the principal route of elimination is renal.

After oral administration of milbemycin oxime in dogs, peak plasma levels occur at about **0.75-24** hours, and decline with a half-life of the unmetabolised milbemycin oxime of **1.5** days. Bioavailability is about 80%.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

Not applicable.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.  
Shelf life after first opening the immediate packaging: 28 days.

### **5.3 Special precautions for storage**

Keep the blister in the outer carton in order to protect from light.

### **5.4 Nature and composition of immediate packaging**

Blister packs made up of OPA/ALU/PVC with aluminium foil in a cardboard box.

#### Pack sizes:

Cardboard box containing 2 tablets. (1 blister strip of 2)  
Cardboard box containing 4 tablets. (2 blister strips of 2 or 1 blister strip of 4)  
Cardboard box containing 8 tablets. (4 blister strips of 2 or 2 blister strips of 4)  
Cardboard box containing 10 tablets. (5 blister strips of 2 or 1 blisters strips of 10)  
Cardboard box containing 16 tablets. (4 blister strips of 4 or 2 blisters strips of 8)  
Cardboard box containing 20 tablets. (10 blisters strips of 2, 5 blister strips of 4 or 2 blister strips of 10)  
Cardboard box containing 24 tablets. (6 blister strips of 4 or 3 blisters strips of 8)  
Cardboard box containing 30 tablets. (3 blister strips of 10 or 15 blisters strips of 2)  
Cardboard box containing 32 tablets. (8 blister strips of 4 or 4 blisters strips of 8)  
Cardboard box containing 40 tablets. (10 blister strips of 4, 5 blisters strips of 8 or 4 blister strips of 10)  
Cardboard box containing 48 tablets. (24 blisters strips of 2, 12 blister strips of 4 or 6 blister strips of 8)  
Cardboard box containing 50 tablets. (5 blister strips of 10)  
Cardboard box containing 96 tablets. (12 blister strips of 8)  
Cardboard box containing 100 tablets. (10 blister strips of 10)

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

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

The veterinary medicinal product should not enter water courses as milbemycin oxime and praziquantel 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 national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Chanelle Pharmaceuticals Manufacturing ltd.,

## **7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: DD/MM/YYYY

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

MM/YYYY

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription. [AT, BG, CY, CZ, DE, DK, EL, ES, FI, FR, HR, HU, IE, IT, NO, PL, PT, RO]

Veterinary medicinal product not subject to prescription. [BE, NL]

Veterinary medicinal product subject to prescription except for some pack sizes. [SE]

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MILBETAB 2.5 mg/25 mg tablets  
MILIPRAZ 2.5 mg/25 mg tablets (NO)

### 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

**Active substances:**

Milbemycin oxime	2.5 mg
Praziquantel	25.0 mg

### 3. PACKAGE SIZE

2 tablets  
4 tablets  
8 tablets  
10 tablets  
16 tablets  
20 tablets  
24 tablets  
30 tablets  
32 tablets  
40 tablets  
48 tablets  
50 tablets  
96 tablets  
100 tablets

### 4. TARGET SPECIES

Dogs (1–5 kg).

### 5. INDICATIONS

For products not subject to veterinary prescription:  
Treatment of mixed infections by tapeworms, hookworm, roundworms, whipworm, eyeworm and lungworms. Prevention of heartworm disease and angiostrongylosis, if concomitant treatment against cestodes is indicated.

### 6. ROUTES OF ADMINISTRATION

Oral use

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use within 28 days.

Once opened use by \_\_\_\_

**9. SPECIAL STORAGE PRECAUTIONS**

Keep the blister in the outer carton in order 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**

Chanelle Pharmaceuticals Manufacturing ltd.,

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

{NATURE/TYPE}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Milbetab



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

2.5 mg milbemycin oxime/tablet

25 mg praziquantel/tablet

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

MILBETAB 2.5 mg/25 mg tablets for small dogs and puppies.  
MILBETAB, 2.5 mg/25 mg tablets for small dogs and puppies. (EE)  
MILIPRAZ 2.5 mg/25 mg tablets for small dogs and puppies ( NO)

### 2. Composition

Each tablet contains:

**Active substances:**

Milbemycin oxime	2.5 mg
Praziquantel	25.0 mg

A white to off white oval shaped tablet with a breakline on both sides. The tablet can be divided into halves.

### 3. Target species

Dogs (1–5 kg).

### 4. Indications for use

For dogs with, or at risk from mixed infections by cestodes, gastrointestinal nematodes, eyeworm, lungworms and/or heartworm. This veterinary medicinal product is only indicated when use against cestodes and nematodes or prevention of heartworm disease/angiostrongylosis is indicated at the same time.

Cestodes:

Treatment of tapeworms: *Dipylidium caninum*, *Taenia* spp., *Echinococcus* spp., *Mesocostoides* spp.

Gastrointestinal Nematodes:

Treatment of:

Hookworm: *Ancylostoma caninum*,

Roundworms: *Toxocara canis*, *Toxascaris leonina*

Whipworm: *Trichuris vulpis*

Eyeworm

Treatment of *Thelazia callipaeda* (see specific treatment schedule under section 3.9 “Administration routes and dosage”).

Lungworms

Treatment of:

*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 3.9 “Administration routes and dosage”),

*Crenosoma vulpis* (Reduction of the level of infection).

Heartworm

Prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes is indicated.

## 5. Contraindications

Do not use in puppies of less than 2 weeks of age and/or weighing less than 0.5 kg.  
Do not use in cases of hypersensitivity to the active substances or to any of excipients

## 6. Special warnings

### Special warnings:

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC 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.

In the absence of risk of co-infection with nematodes or cestodes, a narrow spectrum veterinary medicinal product should be used.

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

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

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

Resistance of *Dipylidium caninum* to praziquantel as well as cases of multi-drug resistance of *Ancylostoma caninum* to milbemycin oxime and resistance of *Dirofilaria immitis* to macrocyclic lactones have been reported in dogs.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method.

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

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

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

### Special precautions for safe use in the target species:

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.

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.

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:

The product may be harmful in case of ingestion, especially by a child.

To avoid accidental ingestion, the product should be stored out of sight and reach of children.

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.

Unused part tablets should be discarded

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:

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 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 with other macrocyclic lactones. Also, no such studies have been performed with breeding animals.

Overdose:

No other signs than those observed at the recommended dose have been observed.

The tolerance of the veterinary medicinal product in young puppies from these breeds has not been investigated.

**7. Adverse events**

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (such as Diarrhoea, Drooling, Emesis) Hypersensitivity reaction Neurological disorders (such as Ataxia, Convulsions, Muscle tremors) Systemic disorders (such as Anorexia, Lethargy)
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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, the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

Oral use.

Minimum recommended dose rate 0.5 mg milbemycin oxime and 5 mg praziquantel per kg are given as a single dose.

The veterinary medicinal product should be administered with or after some food.

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

Underdosing could result in ineffective use and may favour resistance development.

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

<b>Weight</b>	<b>Number of Tablet</b>
0.5 - 1 kg	½ tablet
> 1 – 5 kg	1 tablet
> 5 – 10 kg	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 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 veterinary medicinal 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 veterinary medicinal product can replace the monovalent product containing milbemycin oxime alone.

## **9. Advice on correct administration**

The 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.

Keep the blister in the outer carton in order 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.  
Shelf life after first opening the immediate packaging: 28 days.

## **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 Milbemycin oxime and Praziquantel 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. [AT, BG, CY, CZ, DE, DK, EL, ES, FI, FR, HR, HU, IE, IT, NO, PL, PT, RO]

Veterinary medicinal product not subject to prescription. [BE, NL]

Veterinary medicinal product subject to prescription except for some pack sizes. [SE]

## **14. Marketing authorisation numbers and pack sizes**

MA no:

Blister packs made up of OPA/ALU/PVC with aluminium foil in a cardboard box.

### Pack sizes:

Cardboard box containing 2 tablets. (1 blister strip of 2)

Cardboard box containing 4 tablets. (2 blister strips of 2 or 1 blister strip of 4)

Cardboard box containing 8 tablets. (4 blister strips of 2 or 2 blister strips of 4)

Cardboard box containing 10 tablets. (5 blister strips of 2 or 1 blisters strips of 10)

Cardboard box containing 16 tablets. (4 blister strips of 4 or 2 blisters strips of 8)

Cardboard box containing 20 tablets. (10 blisters strips of 2, 5 blister strips of 4 or 2 blister strips of 10)

Cardboard box containing 24 tablets. (6 blister strips of 4 or 3 blisters strips of 8)

Cardboard box containing 30 tablets. (3 blister strips of 10 or 15 blisters strips of 2)

Cardboard box containing 32 tablets. (8 blister strips of 4 or 4 blisters strips of 8)

Cardboard box containing 40 tablets. (10 blister strips of 4, 5 blisters strips of 8 or 4 blister strips of 10)

Cardboard box containing 48 tablets. (24 blisters strips of 2, 12 blister strips of 4 or 6 blister strips of 8)

Cardboard box containing 50 tablets. (5 blister strips of 10)

Cardboard box containing 96 tablets. (12 blister strips of 8)

Cardboard box containing 100 tablets. (10 blister strips of 10)

Not all pack sizes may be marketed.

## **15. Date on which the package leaflet was last revised**

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

## **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Ltd.,

Loughrea,

Co. Galway,

Ireland

Telephone: +353 (0)91 841788

[vetpharmacoviggroup@chanellegroup.ie](mailto:vetpharmacoviggroup@chanellegroup.ie)

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

## **17. Other information**

Not applicable.