ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemax 2.5 mg/25 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Milbemycin oxime	2.5 mg/chewable tablet
Praziquantel	25.0 mg/chewable tablet

3. PACKAGE SIZE

2 chewable tablets
4 chewable tablets
48 chewable 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.

Weight	Dosage
1 - 5 kg	1 tablet

Single oral administration with or after some food.

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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

Elanco GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/3031

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister/strip

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemax (1-5 kg)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

2.5 mg/25 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Milbemax 12.5 mg/125 mg chewable tablets for dogs
Milbemax 2.5 mg/25 mg chewable tablets for small dogs and puppies

2. Composition

The veterinary medicinal product is available in 2 different sizes:

Name (Type of Tablet)	Milbemycin oxime per tablet	Praziquantel per tablet
Milbemax 2.5 mg/25 mg chewable tablets for small dogs and puppies (oval shaped, dark brown)	2.5 mg	25 mg
Milbemax 12.5 mg/125 mg chewable tablets for dogs (oval shaped, dark brown)	12.5 mg	125 mg

Excipients:
Milbemax chewable tablets for dogs: Propylene glycol (E 1520): 4.54 mg, Iron oxide brown (E 172): 3.29 mg, Butylhydroxyanisole (E 320): 1.32 mg, Propyl gallate (E 310): 0.46 mg, Glycerol (E 422).

Milbemax chewable tablets for small dogs and puppies: Propylene glycol (E 1520): 0.91 mg, Iron oxide brown (E 172): 0.66 mg, Butylhydroxyanisole (E 320): 0.26 mg, Propyl gallate (E 310): 0.09 mg, Glycerol (E 422).

3. Target species

Dogs.

4. Indications for use

For dogs with, or at risk from mixed infections of 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*., 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 “Dosage for each species, routes and method of administration”).

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 “Dosage for each species, routes and method of administration”),
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 the ‘**chewable tablets for small dogs and puppies’** in dogs weighing less than 1 kg.
Do not use the ‘**chewable tablets for dogs’** in dogs weighing less than 5 kg.
Do not use in cases of hypersensitivity to the active substances or to any of excipients.

6. Special warnings

Special warnings:
The possibility that other animals in the same household can be a source of re-infection 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.
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.
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.
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 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.
In the absence of risk of co-infection with nematodes or cestodes, a narrow spectrum veterinary medicinal product should be used.
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.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.
The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

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 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 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
People with known hypersensitivity to any of the ingredients should avoid contact with the veterinary medicinal product.
In case of accidental ingestion of the tablets, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the physician.

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:
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.
Although not recommended, the concomitant use of the veterinary medicinal product with a spot on containing moxidectin and imidacloprid at recommended dose rates following a single application was well tolerated in one experimental study by beagle dogs at the age 11 months or older. Transient neurological adverse reactions (poor proprioception, flaccid

frontal and hind legs, incoordination, slight tremors and high stepping gait of the hind limbs only) were observed after concurrent administration of both veterinary medicinal products in another study conducted in puppies aged 8-12 weeks. Such signs were however not observed in this study after giving the veterinary medicinal product alone. The safety and efficacy of this combination have not been investigated in field studies. In the absence of further studies, caution should be taken in the case of concurrent use with any other macrocyclic lactone. Also, no such studies have been performed with breeding animals, Collies, related breeds and their crosses.

Overdose:
In case of overdosing, no other signs than those observed at the recommended dose have been observed (see section “Adverse events”) but more pronounced.

Major incompatibilities:
Not applicable.

Special precautions for the protection of the environment:
See Special precautions for disposal.

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).

7. Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Digestive tract disorders (such as Diarrhoea, Drooling, Emesis (Vomiting)) Hypersensitivity reaction Neurological disorders (such as Ataxia (Incoordination), Convulsions, Muscle tremors) Systemic disorders (such as Anorexia, Lethargy)

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 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.

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The veterinary medicinal product is administered at a minimum recommended dose rate of 0.5 mg milbemycin oxime and 5 mg praziquantel per kg body weight as a single dose.

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

Weight	**Milbemax 2.5 mg/25 mg chewable tablets for small dogs and puppies**	**Milbemax 12.5 mg/125 mg chewable tablets for dogs**
1 - 5 kg	1 chewable tablet	
≥ 5 – 25 kg		1 chewable tablet
> 25 – 50 kg		2 chewable tablets
> 50 – 75 kg		3 chewable 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 veterinary medicinal product should be administered with or after some food.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister/strip 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 or household waste.

This veterinary medicinal product should not enter water courses as it 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 52127/3030
Vm 52127/3031

Aluminium/aluminium blisters or aluminium strips in an outer cardboard box.

Cardboard box with 1 blister or strip of 2 chewable tablets.
Cardboard box with 1 or 12 blisters or strips of 4 chewable tablets.
Cardboard box with 24 blisters of 4 chewable tablets (Milbemax 12.5 mg/125 mg chewable tablets for dogs).

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 contact details to report suspected adverse reactions:
Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

PV.XXI@elancoah.com
Tel: +44 3308221732

Manufacturer responsible for batch release:
Elanco France S.A.S., 26 rue de la Chapelle, F-68330 Huningue, France

Gavin Hall
Approved: 17 April 2026