ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MilbeVet 2.5 mg/25 mg chewable tablets for small dogs and puppies

Milbemycin oxime / praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

One chewable tablet contains:
Active substances:
Milbemycin oxime 2.5 mg
Praziquantel 25.0 mg
Excipients:
Propylene glycol (E 1520), Iron oxide, brown (E 172), Butylhydroxyanisole (E 320), Propyl gallate (E 310)

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

2 chewable tablets
4 chewable tablets
48 chewable tablets

5. TARGET SPECIES

For dogs weighing at least 1 kg

6. INDICATION(S)

For OTC products
Tablets for the treatment of mixed infections by hookworms, roundworms, eyeworm, lungworm and tapeworms, as well as for heartworm and angiostrongylosis prevention.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Once oral administration with or after some food.
The dosing is dependant on the bodyweight of the dog. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 ^{o}C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. <To be supplied only on veterinary prescription.>

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

<Elanco Logo>

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4194

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister and strip

Please note that the minimum particulars will be appear on the blister or strip with a multi lingual translation, when relevant.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MilbeVet 2.5 mg/25 mg chewable tablets for small dogs and puppies

2.5 mg milbemycin oxime / 25 mg praziquantel

2. NAME OF THE MARKETING AUTHORISATION HOLDER

{Elanco Logo}

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

MilbeVet 12.5 mg/125 mg Chewable Tablets for Dogs
MilbeVet 2.5 mg/25 mg Chewable Tablets for Small Dogs and Puppies

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Milbemycin oxime
Praziquantel

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

MilbeVet chewable tablets for dogs, small dogs and puppies are available in 2 different sizes:

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

Excipients:
Glycerol (E 422), Propylene glycol (E 1520), Iron oxide, brown (E 172), Butylhydroxyanisole (E 320), Propyl gallate (E 310)

4. INDICATION(S)

MilbeVet chewable tablets are indicated in the dog for 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, Thelazia callipaeda, Crenosoma vulpis*

  In *Angiostrongylus vasorum,* the product is indicated for a reduction of the level of infection by immature adult (L5) and adult parasite stages (see specific treatment and disease prevention schedules for *A. vasorum* in section "Dosage for each species, route(s) and method of administration").
  Thelazia callipaeda: please refer to specific treatment schedule under section "Dosage for each species, route(s) and method of administration"

The product can also be used in the 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. ADVERSE REACTIONS

In very rare occasions, hypersensitivity reactions, systemic signs (such as lethargy), neurological signs (such as muscle tremors, ataxia and convulsions) and/or gastrointestinal signs (such as emesis, drooling, diarrhoea and anorexia) have been observed in dogs after administration of the veterinary medicinal product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

MilbeVet chewable tablets are administered at a minimum recommended dose rate of 0.5 mg milbemycin oxime and 5 mg praziquantel per kg body weight.

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

Weight	**MilbeVet 2.5 mg/25 mg chewable tablets for small dogs and puppies**	**MilbeVet 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

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
In cases when heartworm disease prevention is used and at the same time treatment against tapeworm is required, MilbeVet chewable tablets 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 *"product name" (to be completed nationally)* 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.

For the treatment of *Thelazia callipaeda*, milbemcyin oxime should be given in 2 treatments, seven days apart. Where concomitant treatment against cestodes is indicated, the product can replace the monovalent product containing milbemycin oxime alone.

9. ADVICE ON CORRECT ADMINISTRATION

MilbeVet chewable tablet is given once by oral administration with or after some food.

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use 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.

12. SPECIAL WARNING(S)

For animal treatment only.

Special warnings for each target species:
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 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 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.

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 (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 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.
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 veterinarian.

In dogs less than 4 weeks old, tape worm infection is unusual. Treatment of animals less than 4 weeks old with a combination product may therefore not be necessary.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

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 the event of accidental ingestion of the tablets, particularly by a child, seek medical advice and show the doctor the pack and/or the leaflet.
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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has been established during 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:
No interactions were observed when the recommended dose of the macrocyclic lactone selamectin was administered during treatment with the product at the recommended dose.
Although not recommended, the concomitant use of the 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 products in another study conducted in puppies aged 8-12 weeks. Such signs were however not observed in this study after giving MilbeVet 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 of MilbeVet and any other macrocyclic lactone. Also, no such studies have been performed with reproducing animals, Collies, related breeds and their crosses.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{To be completed nationally}

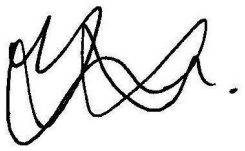
15. OTHER INFORMATION>

Available pack sizes:

Box with 2 chewable tablets in blister
Box with 4 chewable tablets in blister
Box with 48 chewable tablets in blister

Not all pack sizes may be marketed.

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



Approved: 25 March 2021