ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MILBEMAX® tablets for dogs
milbemycin oxime / praziquantel

Broad-spectrum wormer for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains:
Active substances:

Milbemycin oxime	12.5 mg
Praziquantel	125 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

2 tablets
4 tablets
10 tablets
20 tablets
50 tablets
100 tablets

5. TARGET SPECIES

For dogs weighing at least 0.5 kg

6. INDICATION(S)

For OTC products

Tablets for the treatment of infections by hookworms, roundworms, eyeworm, lungworm and tapeworms, as well as for heartworm and lungworm prevention.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Single dose oral administration with or after some food.
The dosing is dependent 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 30 ^{o}C.
Keep the blister in the outer carton in order to protect from light

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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4040

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister and strip

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemax[1]. Tablets for dogs
[[1]in Scandinavia: Milbemax vet]

12.5 mg milbemycin oxime
125 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.

[The lot number and the expiry date will be indicated in each row of tablets. The name and the strengths will appear several times on the blister, to be readable for every tablet. Some countries may require extra text. A dog pictogram and the allowed weight range in kgs is also displayed.]

B. PACKAGE LEAFLET

PACKAGE LEAFLET

MILBEMAX, Tablets for dogs
MILBEMAX, 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

MILBEMAX® tablets for dogs

MILBEMAX® tablets for small dogs and puppies

milbemycin oxime / praziquantel

Broad-spectrum wormer

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

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

Name of Tablet (Type of Tablet)	Milbemycin oxime per tablet	Praziquantel per tablet	Excipients q.s. to one tablet of
MILBEMAX, tablets for small dogs and puppies (white, oblong, divisible)	2.5 mg	25 mg	125 mg
MILBEMAX, tablets for dogs (white, round-shaped)	12.5 mg	125 mg	625 mg

4. INDICATION(S)

MILBEMAX is indicated in the dog for treatment of mixed infections by adult cestodes **and** nematodes of the following species:

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

- Nematodes: *Ancylostoma caninum, Toxocara canis*, *Toxascaris leonina, Trichuris vulpis,. Thelazia callipaeda*

In *Crenosoma vulpis* the product is indicated for a reduction of the level of infection.
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 point “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 ‘**tablets for small dogs and puppies’** in dogs of less than 2 weeks of age and/or weighing less than 0.5 kg
Do not use the ‘**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 and ataxia) and/or gastrointestinal signs (such as emesis, diarrhea, anorexia and drooling) 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

MILBEMAX 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	MILBEMAX for small dogs and puppies	MILBEMAX for dogs
0.5 – 1 kg	½ tablet (oblong, white)	
> 1 - 5 kg	1 tablet (oblong, white)	
> 5 – 10 kg	2 tablets (oblong, white)	1 tablet (round, white)
> 10 – 25 kg		
> 25 – 50 kg		2 tablets (round, white)
> 50 – 75 kg		3 tablets (round, white)

In cases when heartworm disease prevention is used and at the same time treatment against tapeworm is required, MILBEMAX 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 MILBEMAX 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 here concomitant treatment against cestodes is indicated, MILBEMAX can replace the monovalent product containing milbemycin oxime alone.

9. ADVICE ON CORRECT ADMINISTRATION

MILBEMAX is given as a single dose 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 30 °C.
Keep the blister in the outer carton in order to protect from light.
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.
In use shelf-life for half tablets is one month (only valid for Milbemax tablets for small dogs and puppies).

12. SPECIAL WARNING(S)

For animal treatment only.
{To be sold on presentation of a veterinary prescription 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.
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 MILBEMAX 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 next).

Special precautions for use in animals:
As per good veterinary practice, 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 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 MILBEMAX, 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 MILBEMAX.
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.
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.
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.

Pregnancy and lactation:
The product may be used in breeding dogs including pregnant and lactating bitches.

Interaction with other medicinal products and other forms of interaction:
The concurrent use of MILBEMAX with selamectin is well tolerated. No interactions were observed when the recommended dose of the macrocyclic lactone selamectin was administered during treatment with MILBEMAX at the recommended dose. In the absence of further studies, caution should be taken in the case of concurrent use of MILBEMAX and other macrocyclic lactones. Also no such studies have been performed with reproducing animals.

Overdose (symptoms, emergency procedures, antidotes):
No other signs than those observed at the recommended dose have been observed (see Adverse Reactions).

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

September 2020

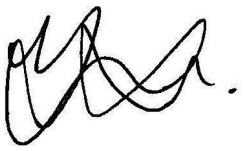
15. OTHER INFORMATION

Available pack sizes:
Box with 2 tablets in blister
Box with 4 tablets in blister
Box with 10 tablets in blister
Box with 20 tablets in blister
Box with 50 tablets in blister

Box with 100 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: 16 September 2020