ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemycin / Praziquantel Tablets 2.5 mg/25 mg Flavoured Tablets for Small Dogs and Puppies

2. STATEMENT OF ACTIVE SUBSTANCES

Milbemycin oxime	2.5 mg
Praziquantel	25.0 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

2, 4, 8, 10, 20, 30, 50, 100, 200 or 500

5. TARGET SPECIES

Dogs

6. INDICATION(S)

In dogs: treatment of mixed infections by gastrointestinal roundworms, tapeworms, hookworms and whipworms and also for the treatment and prevention of the lungworm *Angiostroglyus vasorum* and prevention of the heartworm *Dirofilaria immitis,* where concomitant tapeworm treatment is indicated.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C
Keep blister in the outer carton to protect from light
Any unused half tablets should be returned to the open blister and discarded after 4 weeks.

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.

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

EU Generics Limited
37 Geraldine Road
London
SW18 2NR

16. MARKETING AUTHORISATION NUMBER(S)

Vm 33411/4005

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemycin / Praziquantel Tablets 2.5 mg/25 mg Flavoured Tablets for Small Dogs and Puppies

2. NAME OF THE MARKETING AUTHORISATION HOLDER

EU Generics Limited

3. EXPIRY DATE

4. BATCH NUMBER

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Milbemycin / Praziquantel Tablets 2.5 mg/25 mg Flavoured 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

EU Generics Limited
37 Geraldine Road
London
SW18 2NR

Chanelle Pharmaceuticals Manufacturing Ltd.
Dublin Road
Loughrea
Co. Galway
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemycin / Praziquantel Tablets 2.5 mg/25 mg Flavoured Tablets for Small Dogs and Puppies

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

Milbemycin oxime	2.5 mg
Praziquantel	25.0 mg

4. INDICATION(S)

In dogs: treatment of mixed infections by gastrointestinal roundworms, tapeworms, hookworms and whipworms and also for the treatment and prevention of the lungworm *Angiostroglyus vasorum* and prevention of the heartworm *Dirofilaria immitis*, where concomitant tapeworm treatment is indicated.

5. CONTRAINDICATIONS

Do not use in in puppies of less than 2 weeks of age and/or weighing less than 0.5 kg.
Do not use in case of hypersensitivity to the active substances or to any of the excipients.
See also point "Special precautions for use".

6. ADVERSE REACTIONS

In very rare occasions, systemic signs (such as lethargy), neurological signs (such as muscle tremors and ataxia) and/or gastrointestinal signs (such as emesis, diarrhoea,

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

Minimum recommended dose rate: 0.5 mg of milbemycin oxime and 5 mg of praziquantel per kg are given once orally.

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

Weight	**Tablets**
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 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 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

The product should be administered with or after some food.

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Keep blister in the outer carton to protect from light.
Any unused half tablets should be returned to the open blister and discarded after 4 weeks.
Keep out of sight and reach of children.

12. SPECIAL WARNING(S)

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 developing Heartworm in their blood circulation (microfilaremia) can sometimes lead to the appearance of hypersensitivity reactions that are associated with the release of proteins from dead or dying developing Heartworm and are not a direct toxic effect of the product. The use in dogs suffering from microfilaremia is thus not recommended. A veterinary consultation is advised to exclude the presence of any concurrent infestation of Heartworm. In the case of a positive diagnosis, therapy that treats only adult Heartworms 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.

Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.

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 immediately and show the package leaflet or the label to the doctor.

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), 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:
The product may be used in breeding dogs including pregnant and lactating bitches.

Interaction with other medicinal products and other forms of interaction:
Although the concurrent use of the product with selamectin is well tolerated, in the absence of further studies, caution should be taken in the case of concurrent use of the product and other macrocyclic lactones.

Overdose (symptoms, emergency procedures, antidotes):
No other signs than those observed at the recommended dose have been observed (see section 6).

Incompatibilities:
Not applicable.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
The product should not come into contact with watercourses as this may be dangerous for fish and other aquatic organisms.

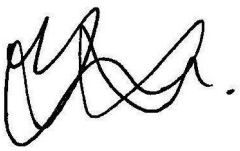
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

2, 4, 8, 10, 20, 30, 50, 100, 200 or 500 tablets

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: 29 January 2020