ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON FOR PACK SIZES OF 1, 2, 4, 6 AND 8 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

On-Defence Wormer 50 mg/144 mg/150 mg Film-coated Tablets for Dogs

(Praziquantel/Pyrantel Embonate/Febantel)

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
50 mg/tablet Praziquantel, 144 mg pyrantel embonate (equivalent to 50 mg pyrantel) and 150 mg/tablet Febantel.

3. PHARMACEUTICAL FORM

Pork Flavoured Tablet

4. PACKAGE SIZE

1, 2, 4, 6, 8 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

For the treatment of mixed infections with gastrointestinal roundworms, hookworms, whipworms and tapeworms in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For oral administration.
1 tablet per 10 kg (22 lbs) bodyweight.
This is equivalent to 15 mg febantel, 14.4 mg pyrantel embonate and 5 mg praziquantel per kilo bodyweight.
The tablets can be divided into halves or quarters.

Dosage table:

Bodyweight (kg)	**Tablets**
3.0-5.0	½
>5.0-7.5	¾
>7.5-10.0	1
>10.0-15.0	1½
>15.0-20.0	2
>20.0-25.0	2½
>25.0-30.0	3
>30.0-35.0	3½
>35.0-40.0	4
>40.0	1 tablet per 10 kg

Administration and Duration of Treatment

It is important to follow the treatment recommendations as presented here. Do not deviate from the recommendations without the advice of your veterinary surgeon. Do not exceed the stated dose.

The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

- For routine control adult dogs should be treated with a single dose every 3 months.
- For the control of *Toxocara*, nursing bitches should be dosed 2 weeks after giving birth and every 2 weeks until weaning.

In case of suspected heavy roundworm infestation, please contact your veterinary surgeon for diagnosis and treatment recommendations.

If there is a risk of re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: In case of accidental ingestion, seek medical advice and show the package leaflet or carton to the physician. Wash hands after use.
Read the package leaflet before use.

Not for use in dogs weighing less than 3 kg or less than 2 weeks of age.
If your dog is receiving other medication, check with your vet before using this product.
Do not use simultaneously with other wormers without veterinary advice.
Do not use in animals with a known allergy to any of the ingredients.
Do not use in pregnant dogs, except under veterinary advice.
If signs of disease persist or appear consult a veterinary surgeon.
Do not exceed the stated dose; in the event of an overdose, seek immediate veterinary advice.
Ensure sources of tapeworm re-infestation (fleas and mice) are removed.

10. EXPIRY DATE

EXP {month/year}
Discard any unused divided tablets.

11. SPECIAL STORAGE CONDITIONS

Do not use after expiry date.
This veterinary medicinal product does not require any special storage conditions

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.

AVM-GSL

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

C&H Generics Ltd
c/o Michael McEvoy and Co
Seville House
New Dock Street
Galway
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 40162/4031

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER FOIL TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

On-Defence Wormer 50 mg/144 mg/150 mg Film-coated Tablets for Dogs

(Praziquantel/Pyrantel Embonate/Febantel)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

C&H Generics Ltd

3. EXPIRY DATE

<EXP {month/year}>

4. BATCH NUMBER

<Batch><Lot> {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
On-Defence Wormer 50 mg/144 mg/150 mg Film-coated Tablets for Dogs

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

Marketing authorisation holder:
C&H Generics Ltd
c/o Michael McEvoy and Co
Seville House
New Dock Street
Galway
Ireland

Manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway. Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

On-Defence Wormer 50 mg/144 mg/150 mg Film-coated Tablets for Dogs

(Praziquantel/Pyrantel Embonate/Febantel)

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each pork flavoured tablet contains
50 mg/tablet Praziquantel, 144 mg pyrantel embonate (equivalent to 50 mg pyrantel) and 150 mg/tablet Febantel.

A pale yellow tablet with a cross breakline on one side.
The tablets can be divided into halves or quarters.

4. INDICATION(S)

For the treatment of mixed infections with roundworms, hookworms, whipworms, and tapeworms of the following species:

Roundworms (Nematodes):
Ascarids (adult and late immature forms): *Toxocara canis*, *Toxascaris leonina*.
Hookworms (adults): *Uncinaria stenocephala*, *Ancylostoma caninum*.
Whipworms (adults)**:** *Trichuris vulpis*.

Tapeworms (Cestodes):
Adult and immature forms of: *Echinococcus* species *(E. granulosus, E. multilocularis), Taenia* species *(T. hydatigena, T. pisiformis, T. taeniformis), Dipylidium caninum*.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity (allergy) to the ingredients (active substances or to any of the excipients).

Do not use simultaneously with piperazine compounds as piperazine may block the action of pyrantel embonate contained in this product. Other worming products may contain piperazine.
Do not use simultaneously with other deworming products without veterinary advice.
Do not exceed the stated dose.

6. ADVERSE REACTIONS

In very rare cases mild and transient digestive tract disorders such as vomiting and/or diarrhoea may occur. In individual cases these signs can be accompanied by nonspecific signs such as lethargy, anorexia, or hyperactivity.

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

For oral administration only.
The recommended dose rate is: 1 tablet per 10 kg (22 lbs) bodyweight.
This is equivalent to 15 mg febantel, 14.4 mg pyrantel embonate and 5 mg praziquantel per kilo bodyweight.

The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.
The tablets can be divided into halves or quarters.

Bodyweight (kg)	Tablets
3.0-5.0	½
>5.0-7.5	¾
>7.5-10.0	1
>10.0-15.0	1½
>15.0-20.0	2
>20.0-25.0	2½
>25.0-30.0	3
>30.0-35.0	3½
>35.0-40.0	4
>40.0	1 tablet per 10 kg

Administration and Duration of Treatment

It is important to follow the treatment recommendations presented below. Do not deviate from these recommendations without the advice of your veterinary surgeon.

Not for use in dogs weighing less than 3 kg or less than 2 weeks of age.
Puppies should be treated at 2 weeks of age and every 2 weeks until 12 weeks of age.
It is advisable to treat the bitch at the same time as the puppies.

-For routine worm control adult dogs should be treated with a single dose every 3 months.
-For the control of *Toxocara*, nursing bitches should be dosed 2 weeks after giving birth and every two weeks until weaning.

In case of suspected heavy roundworm infestation, please contact your veterinary surgeon for diagnosis and treatment recommendation.

If there is a risk for re-infestation (see 'Special Warning(s)' below), the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible.
Discard any unused divided tablets.

10. WITHDRAWAL PERIOD(S)

Not Applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use after expiry date stated on the label.
This veterinary medicinal product does not require any special storage conditions.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.
Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*.
Dogs should also be prevented from scavenging or hunting as part of measures to prevent tapeworm reinfestation.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
If your dog receives other veterinary medicinal products, check with a veterinary surgeon or pharmacist before using this product.

Special precautions for use in animals
Do not exceed the stated dose, especially when treating pregnant bitches.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice and show the package leaflet to the physician.
In the interests of good hygiene, persons administering the tablets directly to the dog, or by adding them to the dog's food, should wash their hands afterwards.

Pregnancy and Lactation:
Consult a veterinary surgeon before treating pregnant animals.
Teratogenic effects attributed to high doses of febantel have been reported in sheep and rats. No studies have been performed in dogs during early pregnancy. Use of the product during pregnancy should be in accordance with a benefit risk assessment by the responsible veterinarian. It is recommended that the product is not used in dogs during the first 4 weeks of pregnancy.
The product may be used in lactating bitches from two weeks after giving birth (see Section 4.9 below).

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized (see section 4.3).
Concurrent use with other cholinergic compounds (e.g. neostigmine, propoxur, and bethanechol) can lead to toxicity.

Other precautions:
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.
For animal treatment only.

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 products should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

15. OTHER INFORMATION

1, 2, 4, 6, or 8 tablets.
Not all pack sizes may be marketed.

Approved 10 March 2022