LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 2 AND 4 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ITCH WORMER Plus XL Tablets for Dogs.
Praziquantel, Pyrantel, Febantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each pork flavoured tablet contains 175 mg Praziquantel, 175 mg Pyrantel (equivalent to 504 mg pyrantel embonate) and 525 mg Febantel.

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

2 or 4 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

For the treatment of mixed infections with roundworms and tapeworms in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

1 tablet per 35 kg bodyweight.
Read the package leaflet before use

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Do not use simultaneously with piperazine compounds as piperazine may block the action of pyrantel embonate contained in the product.
Other worming products may contain piperazine.
Do not use in animals with known hypersensitivity to the active substances or to any of the excipients.
Do not exceed the stated dose.
Consult a veterinary surgeon before treating pregnant animals. It is recommended that the product is not used in dogs during the first 4 weeks of pregnancy.
User Warnings
In case of accidental ingestion, seek medical advice and show the package leaflet or carton to the physician. Wash hands after use.

10. EXPIRY DATE

EXP {month/year}
Unused half tablet must be used within 14 days.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions
Do not use after expiry date.
Do not remove tablets from blister packaging until required for use.
Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the outer carton. Keep the blister in the outer carton.

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

Please refer to package leaflet for disposal advice.

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

Vm 40162/4017

17. MANUFACTURER'S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER FOIL TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ITCH WORMER Plus XL Tablets for Dogs.

Praziquantel, Pyrantel, Febantel.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

C&H Generics Ltd

3. BATCH NUMBER

BN {number}

4. EXPIRY DATE

EXP {month/year}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For Animal Treatment Only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

ITCH WORMER Plus XL 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
Dublin Road
Loughrea
Co. Galway
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ITCH WORMER Plus XL Tablets for Dogs.
Praziquantel, Pyrantel, Febantel

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

Each pork flavoured tablet contains 175 mg Praziquantel, 175 mg Pyrantel (equivalent to 504 mg pyrantel embonate) and 525 mg Febantel. The tablets can be divided into halves.
A yellow coloured oblong tablet with a breakline on both sides.

4. INDICATION(S)

For the treatment of mixed infections with the following roundworms and tapeworms in adult dogs:

Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).

Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).

Whipworms: *Trichuris vulpis* (adults).

Tapeworms: *Echinococcus* species, *(E. granulosus, E. multilocularis), Taenia* species,

(T. hydatigena, T. pisiformis, T. taeniformis) Dipylidium caninum (adult and immature forms).

5. CONTRAINDICATIONS

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.

Other worming products may contain piperazine.

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

Do not exceed the stated dose.

6. ADVERSE REACTIONS

Slight and transient digestive tract disorders such as vomiting and/or diarrhoea may occur in very rare cases. Nonspecific signs such as lethargy, anorexia or hyperactivity can accompany these signs in individual cases.

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.

The recommended dose rates are: 15mg/kg bodyweight febantel, 5 mg/kg pyrantel (equivalent to 14.4 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. This is equivalent to 1 ITCH WORMER Plus XL tablet per 35 kg bodyweight.

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

Dosage table:

Bodyweight (kg)	Tablets
17.5kg	½
>17.5-35.0 kg	1
>35.0-52.5 kg	1 ½
>52.5-70 kg	2

Administration and Duration of Treatment

For oral administration only.

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

For routine treatment a single dose is recommended.

- For routine control adult dogs should be treated 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 for re-infestation, 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

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10. WITHDRAWAL PERIOD

N/A

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date stated on the label after EXP. The expiry date refers to the last day of that month.
Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the outer carton**.** Keep the blister in the outer carton. Unused half tablet must be used within 14 days

12. SPECIAL WARNING(S)

Special warnings for each target species:
Development of parasite resistance to anthelmintics of a certain class can occur following frequent and repeated use of an anthelmintic of that class. Dogs should also be prevented from scavenging or hunting as part of measures to prevent tapeworm reinfestation.

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

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.
Concurrent use with other cholinergic compounds can lead to toxicity.

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. Do not exceed the stated dose when treating pregnant bitches.
The product may be used in lactating bitches from two weeks after giving birth.

Overdose (symptoms, emergency procedures, antidotes):
In safety studies, a single dose of 5 times the recommended dose or greater gave rise to occasional vomiting

User Precautions:

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 a dog or adding them to the dog's food should wash their hands afterwards.

For animal treatment only.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2021

15. OTHER INFORMATION

2 or 4 tablets.

Not all pack sizes may be marketed.

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For Animal Treatment Only

Approved 15 June 2021