PACKAGE LEAFLET

VetUK XL Flavoured Dog Wormer Tablets

175 mg Pyrantel, 175 mg Praziquantel, 525 mg Febantel.

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

VetUK XL Flavoured Dog Wormer Tablets.
175 mg Pyrantel, 175 mg Praziquantel, 525 mg 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 roundworms, hookworms, whipworms and tapeworms of the following species:

Roundworms: *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 products containing piperazine as the anthelmintic effects of pyrantel and piperazine may be antagonized.
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

For oral administration only.
The recommended dose rate is: 5 mg/kg pyrantel (equivalent to 14.4 mg/kg pyrantel embonate), 5mg/kg Praziquantel and 15mg/kg bodyweight Febantel. This is equivalent to 1 tablet per 35kg bodyweight. Tablets can be divided into halves if required.

Dosage table:

Bodyweight (kg)	Tablets
17.5kg	½ Tablet
17.5 - 35 kg	1 Tablet
35 – 52.5kg	1 ½ Tablets
52.5-70 kg	2 Tablets

VetUK Flavoured Dog Wormer Tablets should be used to achieve accurate dosing in dogs weighing less than 17.5 kg.

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

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.

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

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the packaging 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 and inserted back into the outer carton. Keep the blister in the outer carton. Unused half tablets must be used within 14 days.
Do not remove tablets from the blister packaging until required for use.

12. SPECIAL WARNING(S)

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.

Special warnings for each target species:
Dogs may become infected with tapeworms by swallowing fleas; or by eating small rodents, rabbits, hares, or raw offal from affected sheep, goats, pigs deer and cattle. Tapeworm infestation is therefore certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken. Dogs should also be prevented from scavenging or hunting as part of measures to prevent tapeworm reinfestation.
Development of parasite resistance to anthelmintics of a certain class can occur following frequent, repeated use of an anthelmintic of that class.

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

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

Overdose (symptoms, emergency procedures, antidotes), if necessary
The combination of Pyrantel Embonate, Praziquantel and Febantel is well tolerated in dogs. In safety studies, a single dose of 5 times the recommended amount 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.

Other precautions:
Echinococcosis represents a hazard for humans and is a notifiable disease according to the World Organisation for Animal Health (OIE). In the UK, suspected or confirmed Echinococcosis must be reported to the Animal and Plant Health Agency. Specific guidelines on Echinococcosis treatment, case follow-up, and any safeguards for people should 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2021

15. OTHER INFORMATION

2 or 4 tablets.
Not all pack sizes may be marketed.
AVM-GSL
Vm 40162/4020
For Animal Treatment Only.

Distributor:
VetUK Ltd.
Units 7 & 8 Europark
Station Road
Thirsk
North Yorkshire
YO7 1GQ

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
{CARTON FOR PACK SIZES OF 2 AND 4 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VetUK XL Flavoured Dog Wormer Tablets.
175 mg Pyrantel, 175 mg Praziquantel, 525 mg Febantel.

2. STATEMENT OF ACTIVE SUBSTANCES

Each pork flavoured tablet contains 175 mg Praziquantel, 175 mg Pyrantel 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 gastrointestinal roundworms, hookworms, whipworms and tapeworms in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions:
For oral administration only.
Read the package leaflet before use.
The recommended dose is 5 mg/kg Pyrantel (14.4 mg/kg Pyrantel Embonate), 5 mg/kg Praziquantel and 15 mg/kg Febantel. This is equivalent to 1 tablet per 35 kg bodyweight. Tablets can be divided into halves if required.
For dogs weighing less than 17.5kg, VetUK Flavoured Dog Wormer Tablets should be used.

8. WITHDRAWAL PERIOD

N/A

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.

10. EXPIRY DATE

EXP {month/year}

Do not use after expiry date.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special temperature storage conditions.

Each time an unused half tablet is stored, it should be returned to the open blister and inserted back into the outer carton.
Unused half tablets must be used within 14 days

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

Distributor
VetUk Ltd.
Units 7 & 8 Europark
Station Road
Thirsk
YO71GQ info@vetuk.co.uk

16. MARKETING AUTHORISATION NUMBER

Vm 40162/4020

17. MANUFACTURER'S BATCH NUMBER

BN {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER FOIL TEXT}

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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.

Approved: 31/03/21