PACKAGE LEAFLET

VetUK Flavoured Dog Wormer Tablets

50 mg Pyrantel, 50 mg Praziquantel and 150 mg Febentel

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

VetUK Flavoured Dog Wormer Tablets
50 mg Pyrantel, 50 mg Praziquantel and 150 mg Febentel

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

Each pork flavoured tablet contains 50 mg Praziquantel, 50 mg Pyrantel (equivalent to 144 mg pyrantel embonate) and 150 mg Febantel.
The tablets can be divided into halves or quarters.
A pale yellow tablet with a cross breakline on one side.

4. INDICATION(S)

For the treatment of mixed infections with roundworms, tapeworms, hookworms and whipworms 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 piprazine may be antagnoised.
Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.
Do not exceed stated dose when treating pregnant bitches.

6. ADVERSE REACTIONS

In very rare cases slight 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 serious effects or other effects not mentioned in this leaflet, 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 is 5 mg/kg Pyrantel (equivalent to 14.4 mg/kg pyrantel embonate), 5 mg/kg Praziquantel and 15 mg/kg bodyweight Febantel.

This is equivalent to 1 tablet per 10 kg (22 lbs) bodyweight.

Tablets can be divided into quarters if required.

Dosage table:

Body weight	Single Dose Required
3 – 5kg (6.6 – 11lbs)	½ tablet
5 – 10kg (11 – 22lbs)	1 tablet
10 – 15kg (22 – 33lbs)	1½ tablets
15 – 20kg (33 – 44lbs)	2 tablets
20 – 25kg (44 – 55lbs)	2½ tablets
25 – 30kg (55 – 66lbs)	3 tablets

VetUK XL Flavoured Dog Wormer Tablets should be used to achieve accurate dosing in dogs weighing more than 35kg.
It is important to follow the treatment recommendations as presented here. Do not deviate from the recommendations without the advice of your veterinary surgeon.

For routine worm 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 two weeks until weaning.
Puppies should be treated at 2 weeks of age and every 2 weeks until 12 weeks of age. Thereafter they should be treated at 3 month intervals. It is advisable to treat the bitch at the same time as the puppies. Not for use in dogs weighing less than 3 kg. Tapeworm infestation is unlikely in puppies less than 6 weeks of age.
In case of suspected heavy roundworm infestation, please contact your veterinary surgeon for diagnosis and treatment recommendation.

The tablets can be given 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

N/A

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 label after ‘EXP’. The expiry date refers to the last day of that month.
Discard any unused half tablets immediately.
Do not remove tablets from the immediate packaging until required for use.
Keep immediate packaging in outer carton.

12. SPECIAL WARNING(S)

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.
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.

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 praziquantel, pyrantel embonate and febantel is well tolerated in dogs. In safety studies, a single dose of 5 times the recommended dose or greater gave rise to occasional vomiting.

User Warnings:
In case of accidental ingestion, seek medical advice and show the package leaflet or carton 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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2020

15. OTHER INFORMATION

2 tablets.
Not all pack sizes may be marketed.

AVM-GSL

Vm 40162/4015
For animal treatment only.

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

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 2 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VetUK Flavoured Dog Wormer Tablets

50 mg Pyrantel, 50 mg Praziquantel, 150 mg Febantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each pork flavoured tablet contains 50 mg Praziquantel, 50 mg Pyrantel and 150 mg Febantel.

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

2 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Treatment of mixed infections by gastrointestinal roundworms. tapeworms, hookworms and whipworms in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Single dose for oral administration only.
1 tablet per 10 kg bodyweight.

The recommended dose is 5 mg/kg Pyrantel (equivalent to 14.4 mg/kg pyrantel embonate), 5 mg/kg Praziquantel and 15 mg/kg bodyweight Febantel.
This is equivalent to 1 tablet per 10 kg (22 lbs) bodyweight.
Not suitable for dogs weighing less than 3 Kg.
The tablet can be divided in two or four equal doses.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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}

Do not use after expiry date.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special temperature storage conditions. Keep immediate packaging in outer carton. Discard any unused half tablets immediately

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, North Yorkshire, YO7 1GQ, UK

16. MARKETING AUTHORISATION NUMBER

Vm 40162/4015

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

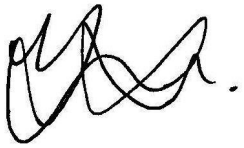
BN {number}

4. EXPIRY DATE

EXP {month/year}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only.



Approved: 17 February 2020