

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 2 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VetUK Cat Wormer Film Coated Tablets
80 mg Pyrantel, 20 mg Praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains Pyrantel 80 mg and Praziquantel 20 mg.

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. PACKAGE SIZE

2 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

For the treatment of mixed infections caused by gastrointestinal roundworms and tapeworms in cats.

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage:

Single dose for oral administration only.

The recommended dose is 20 mg/kg pyrantel (57.5 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. 1 tablet per 4 kg bodyweight.

Not suitable for cats/kittens under 6 weeks old or weighing less than 1kg. Not suitable for use during pregnancy but may be used during lactation.

Read the package leaflet before use.

Tablets can be divided into halves if required.

8. WITHDRAWAL PERIOD

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.

Do not remove tablets from the immediate packaging until required for use.

Keep tablet 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(S)

Vm 40162/4012

17. MANUFACTURER'S BATCH NUMBER

BN {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER FOIL TEXT}

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VetUK Cat Wormer Film Coated Tablets
80 mg Pyrantel, 20 mg Praziquantel

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.

PACKAGE LEAFLET:
VetUK Cat Wormer Film Coated Tablets
80 mg Pyrantel and 20 mg Praziquantel

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 Cat Wormer Film Coated Tablets
80 mg Pyrantel and 20 mg Praziquantel

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

Each film-coated tablet contains Pyrantel 80 mg (equivalent to 230 mg pyrantel embonate) and Praziquantel 20 mg.

A white to off white round, biconvex coated tablet with a breakline on one side and plain on the other side.

The tablets can be divided into halves.

4. INDICATION(S)

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

Roundworms: *Toxocara cati*, *Toxascaris leonina*,

Tapeworms: *Dipylidium caninum*, *Taenia taeniaeformis*, *Echinococcus multilocularis*.

5. CONTRAINDICATIONS

Do not use simultaneously with products containing piperazine as the anthelmintic effects of pyrantel and piperazine may be antagonised.

Do not use in kittens less than 6 weeks of age.

Do not use in animals with known hypersensitivity to the active substances or to any of the excipients.

Not intended for use in cats weighing less than 1kg.

Do not use during pregnancy but may be used during lactation.

6. ADVERSE REACTIONS

Mild and short-lived digestive tract disorders such as excessive salivation and/or vomiting and mild and short-lived disorders of the nervous system such as loss of balance may occur in extremely rare 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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration only.

The recommended dose rate is: 20 mg/kg pyrantel (57.5 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 4 kg bodyweight (8.8lbs) body weight. Tablets can be divided into halves if required.

Dosage table:

Bodyweight	Single Dose Required
1 – 2kg (2.2 – 4.4lbs)	½ tablet
2 – 4kg (4.4 – 8.8lbs)	1 tablet
4 – 6kg (8.8 – 13.2lbs)	1 ½ tablet
6 – 8kg (13.2 17.6lbs)	2 tablet

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 worm control adult cats should be treated every 3 months.

The tablet should be given directly to the cat, but if necessary can be disguised in food.

In roundworm infestation, especially in kittens, complete elimination cannot be expected, so a risk of infection for humans can persist. Repeat treatments should, therefore, be carried out with a suitable roundworm product at 14 day intervals until 2-3 weeks after weaning.

If signs of disease persist or appear, consult a veterinary surgeon.

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.

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.

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

Do not remove tablets from the immediate packaging until required for use.

Keep tablet packaging in outer carton.

12. SPECIAL WARNING(S)

Special warnings for each target species

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

Concurrent use with cholinergic compounds can lead to toxicity.

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.

Development of parasitic resistance to anthelmintics of a certain class can occur following frequent and repeated use of an anthelmintic of that class.

Do not use during pregnancy but may be used during lactation

Overdose (symptoms, emergency procedures, antidotes), if necessary

The combination of pyrantel embonate and praziquantel is well tolerated in cats.

After doses higher than 5 times the recommended dose, signs of intolerance such as vomiting have been observed.

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 cat or adding them to the cat'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

Medicines should not be disposed of via wastewater. The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. 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

15. OTHER INFORMATION

2 tablets.

AVM-GSL

Vm 40162/4012

For animal treatment only.

Distributor

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

Approved 18 February 2020

