

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 2 AND 4 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridaworm 80/20 film-coated Tablets for Cats.

Pyrantel, Praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each film coated tablet contains:

Active substance:

Pyrantel 80 mg

Praziquantel 20 mg

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. PACKAGE SIZE

2 tablets

4 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:

Read the enclosed leaflet before use. Weigh the cat carefully and use this table for the correct dose rate.

Body weight	Tablets
1.0 - 2.0 kg	½
Greater than 2.0 up to 4.0 kg	1
Greater than 4.0 up to 6.0 kg	1 ½
Greater than 6.0 kg	2

1 tablet per 4 kg bodyweight.

For oral administration.

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

Kittens, should be treated at 14 day intervals until 2-3 weeks after weaning as complete ascarid elimination cannot be expected.

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

8. WITHDRAWAL PERIOD

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.

Ensure sources of tapeworm reinfestation (fleas & mice) are removed.

Do not exceed the stated dose. In the event of an overdose, seek immediate veterinary advice.

Do not use in cats less than 6 weeks old or weighing less than 1 kg.

Do not use in pregnant cats.

If your cat is receiving other medication, check with your vet before using this product.

Do not use at the same time as other wormers, or if your cat has an allergy to any of the ingredients.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Do not remove tablets from immediate packaging until required for use. Keep blister in outer carton. Discard any unused half tablets immediately.

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

Disposal: read the 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

Distributor: **Chanelle Animal Health Ltd.**
Rodney Street, 7, Liverpool, L19HZ, United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 40162/4008

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

Ridaworm 80/20 film-coated Tablets for Cats.

Pyrantel, 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

Ridaworm 80/20 film-coated Tablets for Cats.

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

Ridaworm 80/20 film-coated Tablets for Cats.

Pyrantel, Praziquantel

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

Each film coated tablet contains:

Active substance:

Pyrantel 80 mg

(equivalent to 230 mg pyrantel embonate)

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 tablet can be divided into halves.

4. INDICATION(S)

For the treatment of mixed infections caused by the following gastrointestinal roundworms and tapeworms:

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

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

5. CONTRAINDICATIONS

Do not use simultaneously with products containing piperazine.

Do not use simultaneously with other deworming products without veterinary advice.

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.

Do not use during pregnancy.

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 very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

7. TARGET SPECIES

Cats

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

Dosage

The recommended dose 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.

Body weight	Tablets
1.0 - 2.0 kg	½
Greater than 2.0 up to 4.0 kg	1
Greater than 4.0 up to 6.0 kg	1 ½
Greater than 6.0 kg	2

Administration and duration of treatment

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

In ascarid 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 stated on the label after 'EXP'. The expiry date refers to the last day of that month

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

Discard any unused half tablets immediately.

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

Keep blister in outer carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals

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

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

If your cat receives other veterinary medicinal products, check with a veterinary surgeon or pharmacist before using this product.

Do not use simultaneously with any other deworming products.

Do not use in animals with an allergy to the active substances or any of the excipients.

Do not exceed the stated dose; in the event of an overdose seek immediate veterinary advice. After doses higher than 5 times the recommended dose, signs of intolerance such as vomiting have been observed.

Development of parasite resistance to anthelmintics of a certain class can occur after frequent and repeated use of an anthelmintic from that class.

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.

User warnings

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 cat or adding them to the cat'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 (e. g. experts or institutes of parasitology) If the cat has visited areas where *Echinococcus* spp. are prevalent, a veterinarian should be consulted.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2020

15. OTHER INFORMATION

2 or 4 tablets.

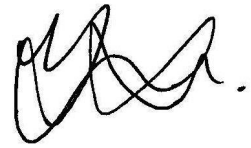
Not all pack sizes may be marketed.

AVM-GSL

Vm 40162/4008

Revised: April 2020
AN: 01019/2019

Distributor: **Chanelle Animal Health Ltd.**
Rodney Street, 7, Liverpool, L1 9HZ, United Kingdom

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 01 April 2020