LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 1, 2, 4, 6, AND 8 TABLETS }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rofectan 230/20 mg Flavoured Film-Coated Tablets for Cats

Pyrantel, Praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains Pyrantel embonate 230 mg and Praziquantel 20 mg.

3. PHARMACEUTICAL FORM

Film-Coated tablets.

4. PACKAGE SIZE

1, 2, 4, 6, and 8 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

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

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

For oral administration. 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.

8. WITHDRAWAL PERIOD(S)

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.

WARNINGS FOR CATS

Ensure sources of tapeworm re-infestation (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.

Do not use if your cat has an allergy to any of the ingredients.

10. EXPIRY DATE

EXP {month/year}

Discard unused half tablets.

11. SPECIAL STORAGE CONDITIONS

Keep blister in outer carton.

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.

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(S)

Vm 40162/4029

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

Rofectan 230/20 mg Flavoured 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.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Rofectan 230/20 mg Flavoured 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

Rofectan 230/20 mg Flavoured Film-Coated Tablets for Cats.

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

Each film-coated tablet contains Pyrantel embonate 230 mg 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.

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 as piperazine may block the action of pyrantel embonate contained in the product.

Other worming products may contain 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 (allergy) to the active substances or to any of the other ingredients (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 extremely rare cases.

7. TARGET SPECIES

Cats

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

Dosage:

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

Bodyweight	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 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 (S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not use after the expiry date stated on the blister and carton. The expiry date refers to the last day of that month.
Unused halved tablets should be discarded.

Do not remove tablets from blister packaging until required for use.
Keep blister in outer carton.
This veterinary medicinal product does not require any special temperature storage restrictions

12. SPECIAL WARNING(S)

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

Special warnings for each target species
Parasitic resistance to a certain class of anthelmintics can occur after frequent and repeated use of an anthelmintic from this 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.

Pregnancy and Lactation:
Do not use during pregnancy but may be used during lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with piperazine compounds.
If your cat receives other veterinary medicinal products, check with a veterinary surgeon or pharmacist before using this product.

Overdose (symptoms, emergency procedures, antidotes):
After doses higher than 5 times the recommended dose, signs of intolerance such as vomiting have been observed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

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

15. OTHER INFORMATION

1, 2, 4, 6 or 8 tablets.
Not all pack sizes may be marketed.

AVM-GSL

Approved 12 January 2021