LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ITCH WORMER for Cats & Kittens 230/20mg Flavoured Tablets
Pyrantel, Praziquantel.

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. PACKAGE SIZE

1, 2 and 4 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

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

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage:

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.

Weight of cat		Single Dose Required
Kgs	lbs	
1.0 - 2.0 kg	2.2 - 4.4 lb	½ tablet
> 2.0 - 4.0 kg	> 4.4 - 8.8 lb	1 tablet
> 4.0 - 6.0 kg	> 8.8 -13.2 lb	1 ½ tablet
> 6.0 kg+	> 13.2lb +	2 tablet

Read the package leaflet before use.

For 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.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Do not use simultaneously with piperazine compounds 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 to the active substances or to any of the excipients.

Do not use during pregnancy.

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

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}

Discard unused half tablets.

11. SPECIAL STORAGE CONDITIONS

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

Keep blister in outer carton.

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

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

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 08749/4068

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

ITCH WORMER for Cats & Kittens 230/20mg Flavoured Tablets
Pyrantel, Praziquantel.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing 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
ITCH WORMER for Cats & Kittens 230/20mg Flavoured Tablets

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ITCH WORMER for Cats & Kittens 230/20mg Flavoured Tablets
Pyrantel, Praziquantel.

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 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 be reported very rarely in spontaneous reports.

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

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.

Weight of cat		**Single Dose Required**
Kgs	**lbs**	
1.0 - 2.0 kg	**2.2 - 4.4 lb**	**½ tablet**
> 2.0 - 4.0 kg	**> 4.4 - 8.8 lb**	**1 tablet**
> 4.0 - 6.0 kg	**> 8.8 - 13.2 lb**	**1 ½ tablet**
> 6.0 kg +	**> 13.2 lb +**	**2 tablet**

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

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 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 strip 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.

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.

Overdose:

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

This veterinary medicinal product may be harmful when ingested, particularly for children.

Avoid accidental ingestion.

Any unused part tablets should be returned to the open blister, inserted back into the outer packaging, and always be used at the next administration. The product should be stored in a safe place out of the sight and reach of children.

In the case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after administering the veterinary medicinal product.

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 products should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater. Ask your veterinary surgeon how to dispose of medicines no longer required.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

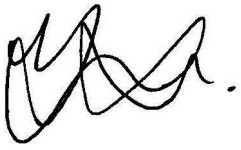
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

1, 2 or 4 tablets.

AVM-GSL

Vm 08749/4068



Approved: 04 May 2024