LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44,48 TABLETS AND ABOVE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cazitel 230/20 mg Flavoured Film-Coated Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PACKAGE SIZE

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48 tablets and more

4. TARGET SPECIES

Cats

5. INDICATION(S)

For products not subject to veterinary prescription:
For the treatment of mixed infections caused by gastrointestinal roundworms and tapeworms.

6. ROUTES OF ADMINSTRATION

Oral Use

7. WITHDRAWAL PERIOD

8. EXPIRY DATE

EXP {mm/yyyy}
Unused half tablets must be discarded

9. SPECIAL STORAGE PRECAUTIONS

Keep blister in outer carton.

10.THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

Distributed by:

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

14. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/5044

15.BATCH NUMBER

Lot{number}

16. SPECIAL WARNING(S), IF NECESSARY

Parasitic resistance to a certain class of anthelmintics can occur after frequent and repeated use of an anthelmintic from this class.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, 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.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

Veterinary medicinal product not subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BLISTER FOIL TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cazitel

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Pyrantel embonate 230mg and Praziquantel 20mg.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}
Unused half tablets must be discarded

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

6. THE WORDS “FOR ANIMAL TREATMENT ONLY

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each film-coated tablet contains Pyrantel embonate 230 mg (equivalent to 79.79mmg of Pyrantel) 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 tablet can be divided into two equal parts.

3. Target Species

Cats

4. Indications for use

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 piperazine compounds.
Do not use in kittens less than 6 weeks of age.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special warnings:
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.
If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration in cats. Local epidemiological information and the living conditions of the cat should be taken into account. It is also important to remove sources of possible re-infection such as fleas and mice.
Parasitic resistance to a certain class of anthelmintics can occur after frequent and repeated use of an anthelmintic from this class.

Special precautions for use in target species:
As the tablets are flavoured, they should be stored in a safe place out of the reach of animals. Animals in a poor condition or heavily infested, which can be manifested by symptoms such as diarrhoea, vomiting, presence of parasites in faeces and vomit, poor hair condition, should be examined by a veterinarian prior to the product administration. For severely debilitated or heavily infested cats, use only according to a benefit/risk assessment by the responsible veterinarian

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label 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.

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 products containing piperazine.

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

Major Incompatibilities:
Not Applicable.

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.

7. Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorder (vomiting and/or hypersalivation) Neurological signs (e.g. ataxia and muscle tremor)

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Oral use.

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.

Body weight	tablets
1.0 - 2.0 kg	½
2.1 - 4.0 kg	1
4.1 - 6.0 kg	1 ½
6.1 - 8.0 kg	2

Administration and duration of treatment
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. Advise on correct administration

To ensure a correct dose, body weight should be determined as accurately as possible

10. Withdrawal periods

Not applicable

11. Special storage precautions

Keep out of the sight and reach of children.Keep blister in outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after Exp. The expiry date refers to the last day of that month.
Unused half tablets must be discarded

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon/pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription

14. Marketing authorisation number and pack sizes

Vm 08749/5044

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 128, 136, 140, 144, 150, 152, 160, 168, 176, 180, 184, 192, 200, 204, 206, 208, 216, 224, 232, 240, 248, 250, 280, 300, 500 or 1000 tablets.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

February 2023

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

Local representatives and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

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