SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Active substances:

Pyrantel embonate 230 mg (equivalent to 80 mg of Pyrantel)
Praziquantel 20 mg

Excipients:

Qualitative composition of excipients and other constituents
Core tablet
Maize starch
Microcrystalline cellulose
Povidone
Magnesium stearate
Colloidal anhydrous silica
Film coat:
Grilled meat flavour
Opadry II White consisting of Polyvinyl Alcohol, Titanium Dioxide (E171), Macrogol 3350 and Talc (E553b)

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. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

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.*

3.3 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.

3.4 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.

3.5 Special precautions for use

Special precautions for safe use in the 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 the interests of good hygiene, persons administering the tablets directly to the cat, or by adding them to the cat's food, should wash their hands afterwards.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
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.

3.6 Adverse events

Cats:

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See 'Contact details' section of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during pregnancy.
Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds.

3.9 Administration routes and dosage

Oral use.
To ensure a correct dosage, body weight 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 in a single administration. 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

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AA51

4.2 Pharmacodynamics

This veterinary medicinal product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The veterinary medicinal product contains two active substances, as follows:

1. Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative
and
2. Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative.

Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis and thereby allow expulsion from the gastro-intestinal (GI) system by peristalsis. Praziquantel is very rapidly absorbed and distributed throughout the parasite. Both in vitro and in vivo studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolization of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.
In this fixed combination, pyrantel is active against the following ascarids: *Toxocara cati*, and *Toxascaris leonina*. Praziquantel is effective against tapeworms in particular *Dipylidium caninum* and *Taenia taeniaeformis.*

Since it contains praziquantel, the veterinary medicinal product is effective against *Echinococcus multilocularis.*

4.3 Pharmacokinetics

Praziquantel is rapidly absorbed, metabolized and distributed in the body. It is also believed to be excreted back into the intestinal lumen by the mucous membrane.
Following administration of the product to cats, peak plasma concentrations of praziquantel were achieved by approximately 2 hours.
Pyrantel is poorly absorbed so it is expected that a large proportion of the administered dose remains in the GIT where it exerts its therapeutic effect and it is excreted largely unchanged in the faeces.
Following administration of the veterinary medicinal product to cats, peak plasma concentrations of pyrantel were achieved by approximately 3 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

Not Applicable

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.Unused half tablets must be discarded.

5.3. Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The product is presented in either:

Individual blisters made up of a PVC/PE/PCTFE white opaque copolymer and a 20µm heatseal lacquer/aluminium containing 2, 4, 6, 8, 10, 12, 14, 16, 18 or 20 tablets.
or
Individual blisters made up of 45µm PVC/aluminium/orientated polyamide and a 20µm heatseal lacquer/aluminium containing 2 or 8 tablets.

The blisters are packed into cartons containing either: 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.
Dispose of waste material in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

7. MARKETING AUTHORISATION NUMBER

Vm 08749/3005

8. DATE OF FIRST AUTHORISATION

10 February 2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription. UK(NI)

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall
Approved: 21 August 2026