

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prazitel 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

Praziquantel 20 mg

Excipients:

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film-coated tablets.

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.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the 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*.

4.3 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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

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 to the physician.

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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, gastrointestinal disorders (vomiting) & neurological signs such as ataxia and muscle tremors have been observed.

The frequency of adverse reactions is defined using the following convention:
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds.

4.9 Amounts to be administered and administration route

Single oral administration.

To ensure administration of a correct dose, 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. 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, praziquantel combinations.
ATC vet code: QP52AA51

5.1 Pharmacodynamic properties

This product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The 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 product is effective against *Echinococcus multilocularis*.

5.2 Pharmacokinetic particulars

Praziquantel is rapidly absorbed, metabolised 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 product to cats, peak plasma concentrations of pyrantel were achieved by approximately 3 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core tablet:

Maize starch,
Microcrystalline cellulose,
Crospovidone

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)

6.2 Major Incompatibilities

Not Applicable

6.3 Shelf life

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

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 08749/4043

9. DATE OF FIRST AUTHORISATION

25 February 2014

10. DATE OF REVISION OF THE TEXT

15 October 2019

Approved 15 October 2019

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date. The signature is stylized and includes a period at the end.