SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Cat Film-coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	**mg per tablet**
Pyrantel Embonate	230.0
Praziquantel	20.0

Relevant Constituents of the Excipients

Titanium Dioxide E171	1.8 mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film-coated tablet.
White to yellowish scored coated tablet. The tablet can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

For the treatment of gastrointestinal roundworms and tapeworms:
Toxocara cati, Toxascaris leonina, Dipylidium caninum, Taenia taeniaeformis.

4.3 Contraindications

Do not use simultaneously with piperazine compounds.
Not intended for use in kittens less than 6 weeks of age.
Do not use during pregnancy.

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 re-occur unless control of intermediate hosts such as fleas, mice etc is undertaken.

As a precautionary measure to prevent the establishment of *Echinococcus multilocula*ris in the UK and Ireland, it is recommended that all dogs and cats entering the country be treated with praziquantel.

4.5 Special precautions for use

i. Special precautions for use in animals

None.

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

In the interests of good hygiene, persons administering the tablets directly to a cat, or by adding them to the cat's food, should wash their hands afterwards.

4.6 Adverse reactions (frequency and seriousness)

Mild and transient digestive tract disorders such as hypersalivation and/or vomiting and mild and transient neurological disorders such as ataxia may occur in extremely rare cases.

4.7 Use during pregnancy and lactation

Not to be used 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 Amount(s) to be administered and administration route

Dosage

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

2 kg bodyweight	½ tablet
4 kg bodyweight	1 tablet
6 kg bodyweight	1 ½ tablets

Administration and Duration of Treatment

Single oral administration. The tablet should be given directly to the animal, but if necessary can be disguised in food.

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

No information.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

An anthelmintic active against gastrointestinal roundworms and tapeworms. The product contains two active ingredients:

1. Pyrantel embonate (pamoate) a tetrahydropyrimidine derivative and

2. Praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative

ATC VetCode: QP52 AA51

Pharmacotherapeutic Group: Anthelmintics, Praziquantel combinations.

5.1 Pharmacodynamic properties

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 gastrointestinal (GI) system by peristalsis.

Praziquantel is very rapidly absorbed into and distributed throughout the parasite. Both in vivo and in vitro 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 vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.

In this fixed combination product pyrantel is active against the following ascarids: *Toxocara cati* and *Toxascaris leonina*. Praziquantel is effective against tapeworms in particular *Dipylidium caninum* and *Taenia taeniaeformis*.

The product has also been shown to be efficacious in the control of hookworms, *Ancylostoma tubaeforme* and *A. braziliense* and the tapeworm *Joyeuxiella pasqualei*, none of which occur naturally in the UK or Ireland but may occasionally be found in imported animals. Since it contains praziquantel, the product is effective against *Echinococcus multilocularis,* which does not occur in the UK or Ireland but is becoming more common in some European countries.

5.2 Pharmacokinetic properties

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Titanium dioxide E171
Maize starch
Microcrystalline cellulose
Povidone K25
Magnesium stearate
Silica colloidial anhydrous
Hypromellose
Polyethylene glycol

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

Do not store above 25°C.
Do not remove tablets from strip packaging until required for use.
Any part used tablets should be discarded.

6.5 Nature and composition of immediate packaging

Container material:	Aluminium foil blister of polyethylene coated aluminium blister
Closure:	Heat seal
Container colour:	Silver or white coloured
Container sizes:	Cartons containing 2, 24 or 96 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Bayer plc
400 South Oak Way
Green Park
Reading
Berkshire
RG2 6AD

8. MARKETING AUTHORISATION NUMBER

Vm 00010/4094

9. DATE OF FIRST AUTHORISATION

03 August 1994

10. DATE OF LAST REVISION OF THE TEXT

May 2018

Approved: 03 May 2018