

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Cat XL Film-coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substances

345.0 mg of Pyrantel embonate
30 mg of Praziquantel

Qualitative composition of excipients and other constituents
Maize starch
Cellulose microcrystalline
Povidone K25
Magnesium stearate
Silica Colloidal anhydrous
Opadry White TF 276U280002
Water purified

Film-coated tablet.

White to yellowish, ellipsoid, biconvex tablet, unscored.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

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

3.3 Contraindications

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 during pregnancy.

Do not use in animals with known hypersensitivity to the active substance or any excipients.

3.4 Special warnings

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.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, due to underestimation of body weight or misadministration of the product.

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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.

Special precautions for the protection of the environment:

Not applicable

3.6 Adverse events

Cats :

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorder ¹ (hypersalivation ¹ , vomiting ¹) Neurological disorder ¹ (ataxia ¹)
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¹ Mild and transient

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use during pregnancy
May be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

For oral use

Dosage

The recommended dose rates are: 57.5 mg/kg pyrantel embonate and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 6 kg bodyweight.

Underdosing could result in ineffective use and may favour resistance development.

To ensure administration of the correct dose, body weight should be determined as accurately as possible.

Weight of cat

Greater than 4 kg up to 6 kg:	1 tablet
Greater than 6 kg up to 12 kg:	2 tablets

If your cats weighs 4 kg or less, Drontal Cat Film-coated Tablets are also available.

Administration and Duration of Treatment

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

The need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

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

No information.

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

Pharmacotherapeutic Group: Anthelmintics, Praziquantel combinations.

1) Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative.

and

2) Praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative, used widely as an anthelmintic for both human and veterinary use.

4.2 Pharmacodynamics

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 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 the pyrantel is active against the following ascarids: *Toxocara cati* and *Toxascaris leonina*. The 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.

Praziquantel is effective against *Echinococcus multilocularis*. *E. multilocularis* does not occur in the UK or Ireland but is becoming more common in some European countries.

4.3 Pharmacokinetics

No data available.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for use: 4 years.

5.3 Special precautions for storage

Do not store above 25°C.

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

5.4 Nature and composition of immediate packaging

Container material: Polyethylene-coated aluminium blister

Closure: Heat seal

Container colour: Silver or white coloured

Container sizes: Cartons containing 2 and 8 tablets in strips of 2 or 8 tablets.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 08007/5066

8. DATE OF FIRST AUTHORISATION

29 January 2004

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

September 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.

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

Gavin Hall

Approved: 22 December 2025