SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Cat XL Film-coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances	**mg per tablet**
Pyrantel embonate	345
Praziquantel	30

Excipients

Titanium dioxide E171 (colouring agent)	2.60

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film-coated tablet.
White to yellowish, ellipsoid, biconvex tablet, unscored.

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 (see also above): *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.
Until sufficient studies have been performed with this combination, 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 *E. multilocularis* in the UK or Ireland, it is recommended that all cats entering the country be treated with praziquantel.

4.5 Special precautions for use

i. Special precautions for use in animals

None known.

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.

Any part-used tablets should be discarded.

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, lactation or lay

Not to be used during pregnancy (see Section 4.3 above) but may be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Piperazine (see Section 4.3 above)

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 6 kg bodyweight.

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.

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

No information.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Drontal Cat XL Tablet is an anthelmintic active against gastrointestinal roundworms and tapeworms.

ATC Vet Code: QP52AA51

Pharmacotherapeutic Group: Anthelmintics, Praziquantel combinations.

The product contains two active ingredients:

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.

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 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.

5.2 Pharmacokinetic properties

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Titanium dioxide E171
Maize starch
Cellulose microcrystalline
Povidone K25
Magnesium stearate
Silica Colloidal anhydrous
Water purified
Hypromellose
Macrogol 4000

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25^{o}C.
Do not remove tablets from strip packing until required for use.

6.5 Nature and composition of immediate packaging

Container material:	Aluminium foil blister or polyethylene-coated aluminium blister
Closure:	Heat seal
Container colour:	Silver or white coloured

Container sizes:	Cartons containing 2, 8, 16, 48 and 96 tablets in strips of 2 or 8 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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4163

9. DATE OF FIRST AUTHORISATION

29 January 2004

10. DATE OF LAST REVISION OF THE TEXT

November 2020

Approved 05 November 2020