

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Plus XL Flavour Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Febantel 525.0 mg
Pyrantel embonate 504.0 mg
Praziquantel 175.0 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Artificial beef flavour Irradiated	408.0 mg
Maize starch	
Lactose monohydrate	
Microcrystalline cellulose	
Povidone K25	
Magnesium stearate	
Sodium lauryl sulfate	
Silica colloidal anhydrous	

Pale brown to brown oval shaped divisible tablet scored on both sides.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the control of the following roundworms and tapeworms in adult dogs:

Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).

Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults)

Whipworms: *Trichuris vulpis* (adults)

Tapeworms: *Echinococcus* spp. *Taenia* spp. and *Dipylidium caninum* (adult and immature forms).

3.3 Contraindications

Do not use simultaneously with piperazine compounds.

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.

Since it contains praziquantel, the veterinary medicinal product is effective against *Echinococcus multilocularis*, which does not occur in the UK or Ireland but is becoming more common in some European countries. As a precautionary measure to prevent establishment of *E multilocularis* in the UK and Ireland, it is recommended that all dogs entering the country be treated with praziquantel.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Any part-used tablets should be discarded.

Do not exceed the stated dose when treating pregnant bitches.

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

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dog:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (e.g., vomiting and diarrhoea) ¹ , Anorexia, Lethargy, Hyperactivity.
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¹Mild 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:

Consult a veterinary surgeon before treating pregnant animals for roundworms.

Lactation:

This veterinary medicinal product may be used during lactation (see Section 3.9 below).

3.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine.

Concurrent use with other cholinergic compounds is not recommended.

3.9 Administration routes and dosage

To ensure a correct dosage, body weight should be determined as accurately as possible.

Dosage

The recommended dose rates are: 15 mg/kg bodyweight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 35 kg bodyweight as follows:

Dosages are as follows:

Body weight (kg)	Tablet quantity
17.5	$\frac{1}{2}$
>17.5 - 35	1
>35 - 52.5	$1 \frac{1}{2}$
>52.5 - 70	2

The veterinary medicinal product should be used to achieve accurate dosing in dogs weighing less than 17.5 kg.

Administration and Duration of Treatment

Oral administration: the tablet(s) can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

For routine treatment a single dose is recommended.

For the control of *Toxocara*, nursing bitches should be dosed 2 weeks after giving birth and every 2 weeks until weaning.

For routine control adult dogs should be treated every 3 months. In the event of a heavy roundworm infestation, a repeat dose should be given after 14 days.

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

The veterinary medicinal product is well tolerated in dogs. In safety studies doses of 5 x or greater gave rise to occasional vomiting.

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

The veterinary medicinal product contains anthelmintics active against roundworms and tapeworms. The veterinary medicinal product contains three active substances:

1. Febantel, a pro-benzimidazole.
2. Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative, and
3. Praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative.

4.1 ATCvet code: QP52AF30

4.2 Pharmacodynamics

In this fixed combination product pyrantel and febantel act synergistically against relevant nematodes (ascarids, hookworms and whipworms) in dogs. In particular, the activity spectrum covers *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum* and *Trichuris vulpis*.

The spectrum of activity of praziquantel covers all important cestode species in dogs, in particular all *Taenia* spp, *Dipylidium caninum*, *Echinococcus granulosus* and

Echinococcus multilocularis. Praziquantel acts against adult and immature forms of these parasites.

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.

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 removal from the gastro-intestinal (GI) system by peristalsis.

Within the mammalian system febantel undergoes ring closure forming fenbendazole and oxfendazole. It is these chemical entities which exert the anthelmintic effect by inhibition of tubulin polymerisation. Formation of microtubules is thereby prevented, resulting in disruption to structures vital to the normal functioning of the helminth. Glucose uptake, in particular, is affected, leading to a depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2-3 days later.

4.3 Pharmacokinetics

No data available.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Do not store above 25°C.

Any part used tablets should be discarded.

5.4 Nature and composition of immediate packaging

Container material:

- PCTFE/PVC-aluminium foil strip
- OPA/Alu/HDPE-aluminium foil strip

Container colour: White and silver

Container sizes: Cartons containing 2, 8, 48 and 96 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 08007/5044

8. DATE OF FIRST AUTHORISATION

31 March 2008

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

August 2026

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: 03 September 2026