

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Plus Flavour Bone Shaped Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Constituents</u>	<u>mg/tablet</u>
Febantel	150.0
Pyrantel embonate	144.0
Praziquantel	50.0

Relevant Constituents of the Excipients

Artificial beef flavour Irradiated	116.5
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For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet.

A pale brown to brown, bone shaped tablet scored on both sides for oral administration to dogs.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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

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).

4.3 Contraindications

Do not use simultaneously with piperazine compounds
Do not exceed the stated dosage when treating pregnant bitches.

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.

4.5 Special precautions for use

- i. Special precautions for use in animals

Any part-used tablets should be discarded.

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

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.

- iii. Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases slight and transient digestive tract disorders such as vomiting and/or diarrhoea may occur. In individual cases these signs can be accompanied by nonspecific signs such as lethargy, anorexia or hyperactivity.

4.7 Use during pregnancy, lactation or lay

Consult a veterinary surgeon before treating pregnant animals for roundworms (see also Section 4.3 above).

The tablets may be used during lactation (see Section 4.8 below).

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

For oral administration only.

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 10 kg bodyweight

Puppies and Small
Dogs:

3-5 kg bodyweight	= ½ tablet
6-10 kg bodyweight	1 tablet

Medium Dogs:

11-15 kg bodyweight	= 1 ½ tablets
16-20 kg bodyweight	= 2 tablets
21-25 kg bodyweight	= 2 ½ tablets
26-30 kg bodyweight	= 3 tablets

Large Dogs:

31-35 kg bodyweight	= 3 ½ tablets
36-40 kg bodyweight	= 4 tablets

Administration and Duration of Treatment

Oral administration, the tablet(s) can be given directly to the dog or disguised in food. Access to normal diet does not need to be limited before or after treatment.

Puppies should be treated at 2 weeks of age and every 2 weeks until 12 weeks of age. Thereafter they should be treated at 3 month intervals. It is advisable to treat the bitch at the same time as the puppies. Not for use in dogs weighing less than 3 kg.

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.

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

Benzimidazoles possess a wide safety margin. Pyrantel is not absorbed systemically to any extent. Praziquantel has a wide safety margin of up to five times the normal dose.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

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

- 1) Febantel
- 2) Pyrantel embonate (pamoate)
and
- 3) Praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative used widely as an anthelmintic for both human and veterinary use.

ATC Vet Code: QP52AC55

5.1 Pharmacodynamic properties

In this fixed combination product pyrantel and febantel act synergistically against all 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.

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 polymerization. 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.

5.2 Pharmacokinetic particulars

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.

Since it contains praziquantel, the product is effective against *Echinococcus multilocularis* which does not occur in the UK but is becoming more common in some European countries.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Lactose monohydrate
Microcrystalline cellulose
Povidone
Magnesium stearate
Sodium laurilsulfate
Colloidal anhydrous silica
Artificial beef flavour irradiated.

6.2 Incompatibilities

None known.

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.

6.5 Nature and composition of immediate packaging

Container material : Polypropylene-coated aluminium foil
:
Container colour : White.

Container sizes : Cartons containing 2, 6, 24, 102 and 108 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 products or waste materials derived from such veterinary medicinal products 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 08007/4167

9. DATE OF FIRST AUTHORISATION

08 June 2000

10. DATE OF LAST REVISION OF THE TEXT

November 2020

Approved 05 November 2020

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date. The signature is stylized and cursive.