SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Plus Flavour Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	**mg per tablet**
Febantel	150.0
Pyrantel embonate	144.0
Praziquantel	50.0

Excipients

Artificial beef flavour irradiated	116.5

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet
A light brown to brown, round, flat tablet, cross scored on one side 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 gastrointestinal tapeworms and roundworms 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., Dipylidium caninum* (adult and immature forms)

4.3 Contraindications

Do not use simultaneously with piperazine compounds.

4.4 Special warnings for each target species

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

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum.* Tapeworm infestation is certain to reoccur 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 tablet should be discarded
Consult a veterinary surgeon before treating pregnant animals for roundworms.
Do not exceed the stated dose when treating pregnant bitches.

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 the dog or by adding it to the dog's food, should wash their hands afterwards.

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.
The product may be used during lactation (see Section 4.9 below).

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

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 (22 lbs) bodyweight.

Puppies and Small Dogs:	
3-5 kg bodyweight	= ½ tablet
>5-10 kg bodyweight	1 tablet
Medium Dogs:	
>10-15 kg bodyweight	= 1 ½ tablets
>15-20 kg bodyweight	= 2 tablets
>20-25 kg bodyweight	= 2 ½ tablets
>25-30 kg bodyweight	= 3 tablets
Large Dogs:	
>30-35 kg bodyweight	= 3 ½ tablets
>35-40 kg bodyweight	= 4 tablets

For oral administration, the tablets can be given to the dog or disguised in food. No starvation is needed 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 two weeks until weaning.

For routine worm control adult dogs should be treated every 3 months.
For routine treatment a single dose is recommended.

In the event of heavy roundworm infestation a repeat dose should be given after 14 days.

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

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

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

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

1. Febantel, a probenzimidazole,

2. Pyrantel embonate (pamoate) a tetrahydropyrimidine derivative,

3. Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative

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5.1 Pharmacodynamic properties

In this fixed combination pyrantel and febantel act 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.* This combination shows synergistic activity in the case of hookworms and febantel is effective against *T. vulpis.*

The spectrum of activity of praziquantel covers all important cestode species in dogs, in particular *Taenia spp*; *Dipylidium caninum; Echinococcus granulosus* and *Echinococcus multilocularis*. Praziquantel acts against all adult and immature forms of these parasites.

Praziquantel is very rapidly absorbed through the parasite's surface and distributed throughout the parasite. Both in vitro and in vivo studies have shown that praziquantel causes severe damage to the parasite integument, resulting in the contraction and paralysis of the parasites. 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 of the nematodes 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 of 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

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Artificial beef flavour irradiated
Maize starch
Lactose monohydrate
Microcrystalline cellulose
Povidone K25
Magnesium sterarate
Sodium laurilsulfate
Silica colloidal anhydrous

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^{o}C.

6.5 Nature and composition of immediate packaging

Container:	Aluminium foil blister or polyethylene-coated aluminium blister
Container colour:	Silver or white coloured
Container sizes:	Cartons containing 2, 8, 24, and 104 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

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

8. MARKETING AUTHORISATION NUMBER

Vm 00010/4158

9. DATE OF FIRST AUTHORISATION

30 April 2008

10. DATE OF LAST REVISION OF THE TEXT

May 2017

Approved 05 May 2017