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:	mg per tablet
Febantel	525.0
Pyrantel embonate	504.0
Praziquantel	175.0
Excipients	
Artificial beef flavour Irradiated	408.0

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

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

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 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).

4.3 Contraindications

Do not use simultaneously with piperazine compounds.

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.

Since it contains praziquantel, the 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.

4.5 Special precautions for use

i) Special precautions for use in animals

Any part-used tablets should be discarded.
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 case of accidental ingestion, seek medical advice and show package leaflet 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.

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 and lactation

Consult a veterinary surgeon before treating pregnant animals for roundworms.
Drontal Plus XL Flavour Tablets 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.
Concurrent use with other cholinergic compounds is not recommended.

4.9 Amount(s) to be administered and administration route

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	½
>17.5 - 35	1
>35 - 52.5	1 ½
>52.5 - 70	2

Drontal Plus Flavour Tablets should be used to achieve accurate dosing in dogs weighing less than 17.5 kg. The dose is equivalent to 1 tablet per 10 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.

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

Drontal Plus XL Flavour Tablets are well tolerated in dogs. In safety studies doses of 5 x or greater gave rise to occasional vomiting.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Anthelmintics, tetrahydropyrimidine

ATC VetCode: QP52AF30
The product contains anthelmintics active against roundworms and tapeworms. The 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.

5.1 Pharmacodynamic Properties

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.

5.2 Pharmacokinetic Properties

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25ºC.
Any part used tablets should be discarded

6.5 Nature and composition of immediate packaging

Container material:	PCTFE/PVC-aluminium foil strip
Container colour:	White
Container sizes:	Cartons containing 2, 8, 48 and 96 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 00010/4153

9. DATE OF FIRST AUTHORISATION

31 March 2008

10. DATE OF LAST REVISION OF THE TEXT

May 2017

Approved 05 May 2017