Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Plus XL Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Active Constituents	mg per tablet
Febantel	525.0
Pyrantel embonate	504.0
Praziquantel	175.0

2.2 Relevant constituents of the Excipients

None

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
Yellow oval shaped 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 tapeworms and roundworms in adult dogs:
Ascarids: *Toxocara canis, Toxascaris leonine* (adult and late immature forms).
Hookworms: *Uncinaria stenocephala*, *Ancylostoma canium* (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

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.

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 Europena countries. As a precautionary measure to prevent establishment of *Echinococcus 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

Special precaution(s) for use in animals

Any part-used tablets should be discarded.
Do not exceed the stated dosage when treating pregnant bitches

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. Drontal Plus XL may be used during lactation (see Section 4.9 below).

4.8 Interaction with other medicinal products and other forms of interactions

Do not use simultaneously with piperazine compounds.

4.9 Amounts 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:

Dogs of 35 kg bodyweight 1 Drontal Plus XL Tablet

Dogs of > 35 kg bodyweight 1 Drontal Plus XL Tablet plus the appropriate quantity of Drontal Plus tablets equivalent to 1 tablet per 10 kg bodyweight

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 worm control adult dogs should be treated every 3 months. 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

Drontal Plus XL is 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 or IMMUNOLOGICAL PROPERTIES

The product contains anthelmintics active against roundworms and tapeworms.

The product contains three active substances:
1) Febantel, a probenzimidazole, chemical name.
2) Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative, and
3) Praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative.

ATC VetCode: 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.
Praziquantel is very rapidly absorbed through the parasite's surface 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 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 to structures vital to the normal functioning of the helminth. Glucose uptake, in particular is affected, leading to 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

Maize Starch
Lactose monohydrate
Microcrystalline Cellulose
Povidone K25
Magnesium Stearate
Sodium laurilsulfate
Silica colloidal anhydrous

6.2 Major incompatibilities

Not applicable.

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 25°C.

Protect from light.

6.5 Nature and composition of immediate packaging

Container: PVC-coated aluminium foil

Container colour: White

Container sizes: Cartons containing 2, 10, 20, 50 and 100 tablets. Not all pack sizes may be marketed.

Contents: Pale yellow tablets

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 SA
Magny-Vernois
70200 Lure
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10521/006/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 October 2003
Date of last renewal: 16 October 2008

10 DATE OF REVISION OF THE TEXT

October 2020