

Drontal Plus Tablets

Introduction



Company name:

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Incorporating the data sheets for the following products:

Drontal Plus Flavour Tablets

Drontal Plus XL Tablets

Presentation

Drontal Plus Flavour Tablet is a pale brown to brown flavoured tablet containing 50 mg praziquantel, 144 mg pyrantel embonate and 150 mg febantel.

Drontal Plus XL Tablet is a pale yellow tablet containing 175 mg praziquantel, 504 mg pyrantel embonate and 525 mg febantel.

Uses

For the control of the following gastrointestinal tapeworms and roundworms of 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 species, *Taenia* species, *Dipylidium caninum* (adults and immature forms).

Dosage and administration

For oral administration only.

The recommended dose rates are: 15 mg/kg bodyweight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel.

1 Drontal Plus Flavour Tablet per 10 kg bodyweight;

1 Drontal Plus XL Tablet per 35 kg bodyweight.

The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

Dosage Guide: Puppies and small dogs

½–2 kg bodyweight = ¼ Drontal Plus Flavour Tablet

2–5 kg bodyweight = ½ Drontal Plus Flavour Tablet

6–10 kg bodyweight = 1 Drontal Plus Flavour Tablet

Dosage Guide: Medium dogs

11–15 kg bodyweight = 1½ Drontal Plus Flavour Tablet

16–20 kg bodyweight = 2 Drontal Plus Flavour Tablet

21–25 kg bodyweight = 2½ Drontal Plus Flavour Tablet

26–30 kg bodyweight = 3 Drontal Plus Flavour Tablet

Dosage Guide: Large dogs

31 - 35 kg bodyweight	= 1 tablet Drontal Plus XL
36 - 40 kg bodyweight	= 1 Drontal Plus XL Tablet plus ½ tablet Drontal Plus Flavour
41 - 45 kg bodyweight	= 1 Drontal Plus XL Tablet plus 1 tablet Drontal Plus Flavour
46 - 50 kg bodyweight	= 1 Drontal Plus XL Tablet plus 1½ tablets Drontal Plus Flavour
51 - 55 kg bodyweight	= 1 Drontal Plus XL Tablet plus 2 tablets Drontal Plus Flavour
56 - 60 kg bodyweight	= 1 Drontal Plus XL Tablet plus 2½ tablet Drontal Plus
61 - 65 kg bodyweight	= 1 Drontal Plus XL Tablet plus 3 tablets Drontal Plus Flavour
66 - 70 kg bodyweight	= 2 Drontal Plus XL Tablets

For routine treatment a single dose is recommended.

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.

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

For routine 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.

Use During Pregnancy and Lactation

Consult a veterinary surgeon before treating pregnant animals for roundworms.

The product may be used during lactation.

Do not exceed recommended dose when treating pregnant bitches.

Contra-indications, warnings, etc

Do not use simultaneously with piperazine compounds.

User safety

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

Pharmaceutical precautions

Do not store above 25°C.

Protect from light.

Do not use after the expiry date.

Any part used tablets should be discarded.

Any unused or waste material should be disposed of in accordance with national requirements.

Packaging Quantities

Drontal Plus Flavour Tablets:	Cartons containing 2, 8, 24, and 104 foil blistered tablets.
Drontal Plus XL Tablets:	Cartons of 2, 10, 20 and 50 foil blistered tablets.

Legal category

NFA-VPS (previously PML)

Further information

The product contains anthelmintics active against roundworms and tapeworms. The product contains three active substances: Febantel, Pyrantel embonate (pamoate) and Praziquantel.

Praziquantel is a partially hydrogenated pyrazino-isoquinoline derivative used widely as an anthelmintic for both human and veterinary use.

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.

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 gastrointestinal 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 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.

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 titanic contraction of the parasite musculature and a rapid vacuolization of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.

Benzimidazoles possess a wide safety margin. Pyrantel is not absorbed systemically to any extent. Praziquantel also has a wide safety margin, beyond five-times overdose.

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

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. As a precautionary measure to prevent establishment of *E. multilocularis* in the UK and Ireland, it is recommended that all dogs entering the country travelling either under the PETS scheme (UK only) or going into quarantine (UK & Ireland) be treated with praziquantel.

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.

Marketing authorisation number

Drontal Plus Flavour Tablets	Vm 00010/4113
Drontal Plus XL Tablets	Vm 00010/4126