

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Tasty Bone Multi-worm XL 525/504/175 mg tablets [IE]
Drontal Dog Flavour XL 525/504/175 mg tablets [BG, CY, EE, EL, HR, LT, LV, PL, RO, SI]
Drontal Plus XL 525/504/175 mg tablets [HU]
Drontal Plus XL Flavour 525/504/175 mg tablets [PT]
Drontal Plus comprimidos con aroma para perros grandes [ES]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substances

525 mg febantel
175 mg pyrantel equivalent to 504 mg pyrantel embonate
175 mg praziquantel

Excipients

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

A light-brown to brown, meat flavoured, bone shaped tablet scored on both sides that can be divided into halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Treatment of mixed infections by nematodes and cestodes of the following species:

Roundworms:

Ascarids (adult and late immature forms) : *Toxocara canis*, *Toxascaris leonina*

Hookworms (adults): *Uncinaria stenocephala*, *Ancylostoma caninum*

Whipworms (adults): *Trichuris vulpis*

Tapeworms (adult and late immature forms):

Echinococcus granulosus

Echinococcus multilocularis

Dipylidium caninum

Taenia spp.

Mesocestoides spp.

For the treatment of the infections caused by the protozoa *Giardia* spp, in puppies and adult dogs.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use during the 1st and 2nd third of pregnancy (see section 4.7)

4.4 Special warnings for each target species

Fleas serve as intermediate hosts for one common type of tapeworm - *Dipylidium caninum*. Dogs may become infected with worms by eating insects (including fleas and lice), birds, small rodents, rabbits or raw offal from affected sheep, goats and cattle. Dogs will continue to be re-infected unless the route of infection is controlled e.g. treating a flea infestation or preventing a dog from scavenging or hunting.

To avoid re-infestation, all animals kept together should be treated at the same time. Cleaning after treatment is crucial to prevent recurrence and spread of infestation. It is particularly important in case of giardiasis. Every area that may be contaminated with faeces or debris should be thoroughly cleaned/washed and disinfected.

4.5 Special precautions for use

Special precautions for use in animals

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Other precautions

Giardia spp. could infect humans, so please ask for medical advice in case your dog is infected.

Since it contains praziquantel, the product is effective against *Echinococcus* spp. which do not occur in all EU member states but are becoming more common in some. Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases mild 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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Teratogenic effects attributed to high doses of febantel administered during early pregnancy have been reported in rats, sheep and dogs.

Use of the product for a 3-day treatment against *Giardia* spp. infections in the 3rd third of pregnancy should be based on a benefit/risk assessment of the veterinarian.

The safety of the product has not been investigated during the 1st and 2nd third of pregnancy. Do not use in pregnant dogs during the 1st and 2nd third of pregnancy (see section 4.3).

A single treatment during the last third of pregnancy or during lactation has been demonstrated safe.

4.8 Interaction with other medicinal products and other forms of interaction

The anthelmintic effects of this product and piperazine containing products may be antagonised when the two drugs are used together.

Concurrent use with other cholinergic compounds can lead to toxicity.

4.9 Amounts to be administered and administration route

For oral administration only.

Dosage

For treatment of dogs, 1 tablet per 35 kg body weight (15 mg febantel, 14.4 mg pyrantel embonate and 5 mg praziquantel/kg body weight).

Dosages are as follows:

Body weight (kg)	Tablet quantity
7-17.5	½
>17.5-35	1
>35-52.5	1 ½
>52.5-70	2

For each additional 17.5 kg bodyweight, administer an additional half tablet.

Administration and Duration of Treatment

The tablets are flavoured and studies have shown that they are palatable and are taken voluntarily by the majority (88%) of dogs tested.

The tablets can be administered with or without food. Access to normal diet does not need to be limited before or after treatment.

Any unused half-tablets should be discarded immediately or returned to the open blisters for use within 7 days.

For roundworms and tapeworms, tablets should be given as a single administration.

A dosing program should be established in consultation with a veterinarian. As a general rule, a standard scheme for adult dogs (above six months of age) is deworming every three months. If a dog owner chooses not to use regular anthelmintic therapy, then fecal examination every three months may be a feasible alternative. In some specific situations such as nursing bitches, young age (less than 6 months), or kennel environments, more frequent treatment may be useful and the advice of a

veterinarian should be sought to establish an appropriate worming protocol. Similarly, in some situations (such as heavy infestations of roundworms or infestation with *Echinococcus* spp.) further treatment may be necessary and a veterinarian can provide information about when additional treatment(s) should be administered.

Not for use in dogs weighing less than 7 kg.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

For treatment against *Giardia* spp. infestations: The recommended dose should be given during three consecutive days.

Clean thoroughly and disinfect the animal's environment to prevent reinfestation, especially in kennel/breeders situations.

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

No signs of adverse reactions were observed in safety studies in dogs and pups following administration of 10 times the recommended dose of the product.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, praziquantel combinations.

ATCvet code: QP52AA51.

5.1 Pharmacodynamic properties

The product is an anthelmintic and giardicide containing as active substances the tetrahydropyrimidine derivative pyrantel (as the embonate salt), the pro-benzimidazole febantel and praziquantel, a partly hydrogenated pyrazinoisoquinoline derivative. It is effective against certain roundworms and tapeworms and *Giardia* spp.

In this fixed combination pyrantel and febantel act synergistically against roundworms (ascarides, hookworms and whipworms) and *Giardia* spp. in dogs. In particular, the action spectrum covers *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*, *Trichuris vulpis* and *Giardia* spp.

The spectrum of activity of praziquantel covers tapeworm species in dogs. In particular, it includes all *Taenia* species, as well as *Dipylidium caninum*, *Mesocestoides* spp., *Echinococcus granulosus* and *Echinococcus multilocularis*. Praziquantel acts against all intestinal stages of these parasites. Additionally, praziquantel activity against some *Giardia* spp. has been reported in the literature.

Pyrantel acts as a nicotinic agonist at acetylcholine receptors, causing spastic paralysis of roundworms via a depolarising neuromuscular block.

The anthelmintic and giardicidal efficacy of febantel is due to its ability to inhibit the polymerisation of tubulin to microtubuli. The resulting structural and functional metabolic disturbances exhaust the parasite's energy reserves and kill it in 2-3 days.

Praziquantel is absorbed very rapidly through the parasite's surfaces and is evenly distributed throughout their bodies. It causes severe damage of their integument, leading to disruption of metabolism and subsequently to death.

5.2 Pharmacokinetic particulars

Praziquantel is absorbed almost completely in the small intestine following oral administration to dogs. Absorption is very rapid reaching maximum serum levels within 0.5 to 2 hours. After absorption, the drug is widely distributed through the body. Plasma protein binding is high. Praziquantel is rapidly metabolised in the liver leading to inactive metabolites. In dogs, metabolites are eliminated by urine (66 % of an oral dose) and via the bile (15%) in the faeces. Elimination half-life in dogs is about 3 hours.

Pyrantel (as embonate), being a low water-soluble compound, is poorly absorbed in the gastrointestinal tract, reaching the final parts of the intestine. The absorbed drug is extensively metabolised and the parent compound/metabolites are excreted by urine.

Febantel is a pro-drug that after oral administration and oral absorption is metabolised to fenbendazole and oxfendazole, the chemical entities exerting the anthelmintic effect. The active metabolites are excreted via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Lactose monohydrate
Microcrystalline cellulose
Povidone K25
Magnesium stearate
Sodium laurilsulfate
Colloidal anhydrous silica
Croscarmellose sodium
Meat flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life of half-tablets after first opening the immediate packaging: 7 days

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Container material: Blisters formed from PA/Alu/PE foil and sealed with Alu/PE foil.

Container sizes: Cartons containing 2, 4, 8, 24, 48 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

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

Date of last renewal:

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE