

Drontal Dog Tasty Bone 150/144/50 mg Tablets **Drontal Dog Tasty Bone XL 525/504/175 mg tablets**

Species:Dogs

Therapeutic indication:Pharmaceuticals: Endoparasiticides: Anthelmintics for dogs

Active ingredient:Febantel, Praziquantel, Pyrantel Embonate

Product:Drontal® Dog Tasty Bone 150/144/50 mg Tablets

Drontal® Dog Tasty Bone XL 525/504/175 mg tablets

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Incorporating:Drontal Dog Tasty Bone 150/144/50 mg Tablets

Drontal Dog Tasty Bone XL 525/504/175 mg tablets

Presentation

Drontal Dog Tasty Bone 150/144/50 mg tablets are light-brown to brown, meat flavoured, bone shaped tablets scored on both sides that can be divided into halves. Each tablet contains 150 mg febantel, 50 mg pyrantel (equivalent to 144 mg pyrantel embonate) and 50 mg praziquantel.

Drontal Dog Tasty Bone XL 525/504/175 mg tablets are light-brown to brown, meat flavoured, bone shaped tablet scored on both sides that can be divided into halves. Each tablet contains 525mg febantel, 175mg pyrantel (equivalent to 504mg pyrantel embonate) and 175mg praziquantel.

Uses

For the treatment of mixed infections by the following species of nematodes and cestodes in dogs:

Roundworms

- Ascarids (adult and late immature forms): *Toxocara canis*, *Toxascaris leonina*
- Hookworms (adults): *Uncinaria stenocephala*, *Ancylostoma caninum*
- Whipworms (adults): *Trichuris vulpis*

Tapeworms (adult and immature forms)

- *Echinococcus granulosus*, *Echinococcus multilocularis*, *Dipylidium caninum*, *Taenia* spp.

Dosage and administration

For oral administration only.

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

Dosage: For treatment of dogs administer 1 Drontal Dog Tasty Bone 150/144/50 mg tablets per 10 kg body weight (15 mg febantel, 14.4 mg pyrantel embonate and 5 mg praziquantel/kg body weight) or 1 Drontal Dog Tasty Bone XL 525/504/175 mg tablets per 35 kg body weight (15 mg febantel, 14.4 mg pyrantel embonate and 5 mg praziquantel/kg body weight). .

Dosages are as follows

Drontal Tasty Bone Tablets

Body weight (kg)	Tablet quantity
2-5	½
>5-10	1
>10-15	1 ½
>15-20	2

For each additional 5 kg body weight, administer an additional half tablet.

Drontal Tasty Bone XL Tablets

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.

Tablets should be given as a single administration.

The advice of a veterinarian should be sought regarding the need for and frequency of repeat treatment.

Drontal Dog Tasty Bone 150/144/50 mg tablets: Not for use in dogs weighing less than 2 kg.

Drontal Dog Tasty Bone XL 525/504/175 mg tablets: Not for use in dogs weighing less than 7 kg.

Use During Pregnancy and Lactation

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

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

Contra-Indications, Warnings etc).

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

Contra-indications, warnings, etc

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.

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.

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

To minimise the risk of re-infestation and new infestation, excreta should be collected and properly disposed of for 24 hours following treatment.

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.

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

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

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

10 times the recommended dose of the product was tolerated without signs of adverse reactions in dogs and pups.

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.

User Safety

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.

Environmental Safety

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Pharmaceutical precautions

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

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

Shelf life of half-tablets: 7 days

Drontal Dog Tasty Bone 150/144/50 mg tablets: After opening the blister, remaining half-tablets should be wrapped in aluminium foil and returned to the open blister.

Drontal Dog Tasty Bone XL 525/504/175 mg tablets: Part tablets should be discarded immediately or returned to the open blister until used.

Legal category

Legal category: NFA-VPS

Packaging quantities

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

Container sizes:

Drontal Dog Tasty Bone 150/144/50 mg tablets: Cartons containing 2, 6, 24 or 102 tablets.

Drontal Dog Tasty Bone XL 525/504/175 mg tablets: Cartons containing 2, 8, 48 tablets.

Further information

Pharmacotherapeutic group: Anthelmintics, praziquantel combinations.

ATCvet code: QP52AA51.

The product is an anthelmintic 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.

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

The spectrum of activity of praziquantel covers tapeworm species in dogs. In particular, it includes all *Taenia* species, as well as *Multiceps multiceps*, *Dipylidium caninum*, *Echinococcus granulosus* and *Echinococcus multilocularis*. Praziquantel acts against all intestinal stage of these parasites.

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

The anthelmintic efficacy of febantel is due to its ability to inhibit the polymerisation of tubuline 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.

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.

Marketing Authorisation Number

Drontal Dog Tasty Bone 150/144/50mg Tablets Vm 00010/4187

Drontal Dog Tasty Bone XL 525/504/175 mg
Tablets Vm 00010/4214

Significant changes

GTIN

GTIN description:Drontal Dog Tasty Bone 150/144/50 mg Tablets (2 Tablets)

GTIN:04007221036197

GTIN description:Drontal Dog Tasty Bone 150/144/50 mg Tablets (6 Tablets)

GTIN:04007221036395

GTIN description:Drontal Dog Tasty Bone 150/144/50 mg Tablets (24 Tablets)

GTIN:04007221036210

GTIN description:Drontal Dog Tasty Bone 150/144/50 mg Tablets (102 Tablets)

GTIN:04007221040033

GTIN description:Drontal Dog Tasty Bone XL 525/504/175 mg tablets (48 Tablets)

GTIN:04007221047629

GTIN description:Drontal Dog Tasty Bone XL 525/504/175 mg tablets (8 Tablets)

GTIN:04007221047643

GTIN description:Drontal Dog Tasty Bone XL 525/504/175 mg tablets (2 Tablets)

GTIN:04007221047636

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