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Vetoquinol UK Ltd

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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

Product index: Drontal Dog Tasty Bone Tablets

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 1/2
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>52.5-70	2
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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.

After opening the blister, remaining half-tablets should be wrapped in aluminium foil and returned to the open blister. Shelf life of half-tablets: 7 days.

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.

Contra-indications, warnings, etc

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 “Special warnings” section).

Special warnings

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.

Special precautions for use in the target species:

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 reinestation and new infestation, excreta should be collected and properly disposed of for 24 hours following treatment.

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:

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.

Adverse reactions

Dogs :

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorder Anorexia, Lethargy, Hyperactivity.
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1 Mild and transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details

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 "Contraindications" section).

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

Interaction with other medicinal products and other forms of interaction

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

Overdose

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.

Disposal

UK: Medicines should not be disposed of via wastewater.

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Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

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.

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:

Container sizes: Cartons containing 2, 4, 6, 24, 102, 312 tablets.

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

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder (if different from distributor)

Marketing Authorisation Holder

Vetoquinol UK Ltd, Steadings Barn, Pury Hill Business Park. Towcester NN12 7LS

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 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.

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	UK(GB):
	UK(NI): \
Drontal Dog Tasty Bone XL 525/504/175 mg Tablets	UK(G
	UK(N

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