1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Tasty Bone Multi-worm XL 525/504/175 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Actives substances:
525 mg febantel
175 mg pyrantel equivalent to 504 mg pyrantel embonate
175 mg praziquantel

Excipients:

Qualitative composition of excipients and other constituents
Maize starch
Lactose monohydrate
Microcrystalline cellulose
Povidone K25
Magnesium stearate
Sodium laurilsulfate
Silica, colloidal anhydrous
Croscarmellose sodium
Meat flavour

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each 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.

3.3 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 3.7).

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe 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.

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.

Special precautions for the protection of the environment:

Not applicable.

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.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (e.g., vomiting and diarrhoea)[1], Anorexia, Lethargy, Hyperactivity.

[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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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 by the responsible 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 3.3).

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

3.8 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.

3.9 Administration routes and dosage

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.

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 a correct dosage, 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AA51.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 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.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Any unused half-tablets should be discarded immediately or returned to the open blister for use within 7 days.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/014/002

8. DATE OF FIRST AUTHORISATION

08/09/2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07/06/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription:

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).