PACKAGE LEAFLET

Drontal®

Dog Tasty Bone XL

525/504/175 mg tablets

febantel/pyrantel embonate/praziquantel

For treatment of roundworms and tapeworms

Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder:

Bayer plc
400 South Oak Way
Green Park
Reading
RG2 6AD
UK
Tel: 0118 206 3000

Bayer Ltd
The Atrium
Blackthorn Road
Dublin 18
Ireland
Tel: 01 299 9313

Manufacturer responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH,
Projensdorfer Str. 324, 24106 Kiel, Germany

Name of the veterinary medicinal product

Drontal Dog Tasty Bone XL 525/504/175 mg tablets
febantel/pyrantel embonate/praziquantel

Statement of the active substance(s) and other ingredient(s)

Each tablet contains:
Active Substances
525 mg febantel
175 mg pyrantel equivalent to 504 mg pyrantel embonate
175 mg praziquantel
A light-brown to brown, meat flavoured, bone shaped tablet scored on both sides that can be divided into halves.

Indication(s)

Treatment of mixed infections by nematodes and cestodes of the following species:
Roundworms:
Ascarids (adults 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.

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 Special warnings).

Adverse reactions

In very rare cases mild and transient digestive tract disorders (e.g. vomiting) may occur. The frequency of adverse reactions is defined using the following convention:
– very rare (less than 1 animal in 10,000 animals, including isolated reports).
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Target species

Dogs

Dosage for each species, route(s) and method of administration

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 of (approximately, 9 of every 10) dogs tested. 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*) retreatment may be necessary and a veterinarian can provide information about when retreatment should be administered.
Not for use in dogs weighing less than 7 kg.

Advice on correct administration

The tablets can be administered with or without food. Access to normal diet does not need to be limited before or after treatment.
Part tablets should be discarded immediately or returned to the open blister until used.

Withdrawal period

Not Applicable

Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Keep the container in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
Shelf life of half-tablets: 7 days.

Special warning(s)

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
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.
To minimise the risk of reinfestation 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 this package leaflet or the label to the physician.
In the interests of good hygiene, one should wash their hands after handling the tablets.

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 and is a notifiable disease to the World Organisation for Animal Health (OIE). When *Echinococcosis* is suspected, specific guidelines on the treatment and follow-up, and on the safeguard of persons, should be obtained from your relevant competent authority.

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

Interaction with other medicinal products:

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

Overdose (symptoms, emergency procedures, antidotes):

Up to 10 times the recommended dose of the product was tolerated without problems in dogs and pups.

Special precautions for the disposal of unused product or waste materials, if any

Any unused tablets or waste materials derived from this product should be disposed of in accordance with local requirements.

Date on which the package leaflet was last approved

September 2017

Other information

Container sizes: Cartons containing 2, 4, 8, 24, 48 tablets.
Not all pack sizes may be marketed.
For animal treatment only.

UK only

NFA-VPS

Vm 00010/4214

Ireland only

CAM

Companion Animal Medicine

VPA 10021/069/002

Bayer