Package Leaflet for:

Drontal®

Dog Tasty Bone 150/144/50 mg tablets

Name and address of the Marketing Authorisation Holder and of the Manufacturer

UK
Marketing Authorisation Holder:
Bayer plc, Animal Health Division
Bayer House
Strawberry Hill
Newbury, Berkshire
RG14 1JA
UK
Tel. 01635 563000
IE
Marketing Authorisation Holder:
Bayer Ltd, The Atrium
Blackthorn Road
Dublin 18
Ireland
Tel. 01 299 9313
Manufacturer:
KVP Pharma + Veterinar Produkte
GmbH, Projensdorfer Str, 324, 24106
Kiel, Germany

The name of this veterinary medicinal product is:
Drontal Plus Flavour Tablets for Dogs 150/144/50mg tablets
febantel, pyrantel embonate, praziquantel

The Statement of the active substance(s) and other ingredient(s):
Each tablet contains
Active Substances
150.0mg Febantel
50mg Pyrantel equivalent to 144.0mg Pyrantel embonate
50.0mg Praziquantel
A pale 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 (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 spp., Taenia spp., Dipylidium caninum

Contraindications

Do not use in case of hypersensitivity to the active substances or to any of the excipients
Do not use during the 1st and 2nd thirds of pregnancy (see Special Warnings)

Adverse reactions

In very rare cases mild and transient digestive tract disorders (eg vomiting) and 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 serious side effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

Target species

Dogs
Dosage for each species, route(s) and method administration
For oral administration only

Dosage

For treatment of dogs, 1 tablet per 10 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
2-5	½
>5-10	1
>10-15	1 ½
>15-20	2

For each additional 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 faecal examination every three months may be a feasible alternative. In some specific situations such as nursing bitches, young age (less than 6months), or kennel

environments, more frequent treatments 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 Echinococcal) retreatments may be necessary and a veterinarian can provide information about when retreatment should be administered.

Not for use in dogs weighing less than 2kg.

Advice on correct administration
The tablets can be administered with or without food. Access to normal diets does not need to be limited before or after treatment.

Withdrawal period
Not applicable

Special storage precautions
Keep out of the sign and reach of children.

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date with is stated on the carton and blister after EXP. The expiry date refers to the last day of the month.

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

Special Warning(s)
For animal treatment only.
Fleas serve as intermediate hosts for one common type of tapeworm – Dipylidium caninum. Tapeworm infestation is certain to reoccur unless, control of intermediate hosts such as fleas, mice, is undertaken.
To minimise the rest of reindentation and new infestation, excreta should be collected and properly disposed of for 24 hours following treatment.

<u>Special precaution to be taken by the person administering the veterinary medicinal product to animals.</u>
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

In the interest of good hygiene, one should wash their hands after handling the tablets.

<u>Other precautions</u>
Since it contains praziquantel, the product is effective against Echinococcus spp which does not occur in all EU member states but is 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.

<u>Pregnancy and lactation:</u>

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).

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

Date on which the package leaflet was last approved
September 2014

Other information
Container sizes: Cartons containing 2, 4, 6, 24, 102, 312 tablets.
Not all pack sizes may be marketed.

UK Only
NFA-VPS

Vm 00010/4187

IE Only
CAM
Companion Animal Medicine
VPA 10021/69/001

Bayer