

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE - Carton**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Drontal Dog Tasty Bone 150/144/50 mg tablets

### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

One tablet contains:

150 mg febantel

144 mg pyrantel embonate (equivalent to 50 mg pyrantel)

50 mg praziquantel

### **3. PACKAGE SIZE**

2 tablets

4 tablets

6 tablets

24 tablets

102 tablets

312 tablets

### **4. TARGET SPECIES**

Dogs.

### **5. INDICATION(S)**

For products not subject to veterinary prescription–

Treatment of mixed infections by roundworms and tapeworms.

[Indications should be included in countries where the product is available without prescription. Where the product is subject to prescription this text is not required but may be included to more easily determine the correct product. However, if space is limited (e.g., for multi-language packages) the indications should not be included for countries where the product is prescription only.]

### **6. ROUTES OF ADMINISTRATION**

Oral use.

1 tablet per 10 kg (with bone-shaped tablet pictogram/graphic)

### **7. WITHDRAWAL PERIODS**

### **8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use half tablet within 7 days.

## **9. SPECIAL STORAGE PRECAUTIONS**

Half-tablets should be wrapped in aluminium foil and returned to the open blister.

## **10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

## **11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

## **13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Vetoquinol UK Limited  
Steadings Barn  
Pury Hill Business Park  
Nr. Alderton  
Towcester  
Northamptonshire  
Northants  
NN12 7LS

## **14. MARKETING AUTHORISATION NUMBER**

Vm 08007/5003

## **15. BATCH NUMBER**

Lot {number}

## **16. SPECIAL WARNING(S), IF NECESSARY**

Keep the blister in the outer carton.

## **17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: Read package leaflet.

## **18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

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**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS -Blister sheets**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**Drontal Dog Tasty Bone**

(dog pictogram)

**2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

febantel	150 mg
pyrantel embonate	144 mg
praziquantel	50 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

*Vetoquinol logo*

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Drontal Dog Tasty Bone 150/144/50 mg tablets

### **2. COMPOSITION**

Each tablet contains:

Active substances:

150 mg febantel

50 mg pyrantel equivalent to 144 mg pyrantel embonate

50 mg praziquantel

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

### **3. TARGET SPECIES**

Dogs.

### **4. INDICATIONS FOR USE**

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.

### **5. 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).

## 6. SPECIAL WARNINGS

### 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 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 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.

### 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.

## **7. ADVERSE EVENTS**

Dogs :

Very rare ( $<1$ animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (e.g., vomiting and diarrhoea) <sup>1</sup> , Anorexia (loss of appetite), Lethargy, Hyperactivity.
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<sup>1</sup>Mild and transient.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder ~~<or the local representative of the marketing authorisation holder>~~ using the contact details at the end of this leaflet, or via your national reporting system: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

## **8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF 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	$\frac{1}{2}$
>5-10	1
>10-15	1 $\frac{1}{2}$
>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.

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

Not for use in dogs weighing less than 2 kg.

To ensure a correct dosage, body weight should be determined as accurately as possible.

## **9. 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.

## **10. WITHDRAWAL PERIODS**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight 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 which is stated on the carton and blister after Exp. The expiry date refers to the last day of that month.

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.

## **12. SPECIAL PRECAUTIONS FOR DISPOSAL**

Medicines should not be disposed of via wastewater..

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 applicable national collection systems. These measures should help to protect the environment.

[UK: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.](#)

## **13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

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

#### 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08007/5003

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

Not all pack sizes may be marketed.

#### 15. PID LINK (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

#### 16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Vetoquinol UK Limited  
Steadings Barn  
Pury Hill Business Park  
Nr. Alderton  
Towcester  
Northamptonshire NN12 7LS  
United Kingdom

Manufacturer responsible for batch release:

KVP Pharma und Veterinär Produkte GmbH, 24106 Kiel, Germany

#### 17. OTHER INFORMATION

*Gavin Hall*

Approved 24 January 2025