

PARTICULARS TO APPEAR ON THE OUTER PACKAGE Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One tablet contains:

525 mg febantel

504 mg pyrantel embonate (equivalent to 175 mg pyrantel)

175 mg praziquantel

3. PACKAGE SIZE

2 tablets

4 tablets

8 tablets

24 tablets

48 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 35 kg (with bone-shaped tablet pictogram/graphic)

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyyr} Once opened, use half tablet within 7 days.

9. SPECIAL STORAGE PRECAUTIONS

Half-tablets should be stored in the original pack.

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

NN12 7LS

United Kingdom

14. MARKETING AUTHORISATION NUMBER

Vm 08007/5004

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Keep the blister in the outer carton.

For animal treatment only

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

POM-V

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS - Blister sheets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Dog Tasty Bone XL

(dog pictogram)

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

febantel	525 mg
pyrantel embonate	504 mg
praziquantel	175 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 XL 525/504/175 mg tablets

2. COMPOSITION 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.

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 for each target species:

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 animals:

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.

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, 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. 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.

Concurrent use with other cholinergic compounds can lead to toxicity.

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) ¹ , Anorexia (loss of appetite), Lethargy, Hyperactivity.
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¹Mild 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 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	$\frac{1}{2}$
>17.5 -35	1
>35 -52.5	$1 \frac{1}{2}$
>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.

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

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Not for use in dogs weighing less than 7 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.

Any unused half-tablets should be discarded immediately or returned to the open blisters for use within 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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14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08007/5004

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

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

For animal treatment only.

Gavin Hall
Approved 24 January 2025