ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Dog Tasty Bone 150/144/50 mg tablets
febantel/pyrantel embonate/praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains:

150 mg febantel
[for all member states except FR:]
144 mg pyrantel embonate (equivalent to 50 mg pyrantel)
[for FR only:]
50 mg pyrantel (as embonate) 50 mg praziquantel

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

2 tablets
4 tablets
6 tablets
24 tablets
102 tablets
312 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For OTC products - For treatment of 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.]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

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

8. WITHDRAWAL PERIOD (S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Shelf life of half-tablets: 7 days.

11. SPECIAL STORAGE CONDITIONS

Left-over half-tablets should be wrapped in aluminium foil and returned to the open blister.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

[Prescription status to be completed nationally]

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4164

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister sheets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Dog Tasty Bone [IE, UK]

150/144/50 mg
febantel/pyrantel embonate/praziquantel

1  (bone-shaped tablet pictogram) tablet per 10 kg


(dog pictogram)

[Applicant's note: The applicant proposes to include only the invented name on the blisters. The strength is shown by the "10 kg"and the numeric text , the pharmaceutical form is shown by the bone-shaped tablet pictogram and the word "tablet"on the blister, and the dog pictogram shows the target species when not part of the local invented name]

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited logo

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Drontal Dog Tasty Bone 150/144/50 mg tablets

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

Manufacturer responsible for batch release:
KVP Pharma und Veterinär Produkte GmbH, 24106 Kiel, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Dog Tasty Bone 150/144/50 mg tablets

febantel/pyrantel embonate/praziquantel

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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.

4. 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.

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 WARNING(S)” section).

6. ADVERSE REACTIONS

In very rare cases slight and transient digestive tract disorders such as vomiting and/or diarrhoea may occur. In individual cases these signs can be accompanied by nonspecific signs such as lethargy, anorexia or hyperactivity.

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.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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	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.

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

For IE and UK only: this statement replaces the above statement
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 2 kg.

To ensure administration of a correct dose, 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 PERIOD

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 WARNING(S)

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.

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 "**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 (symptoms, emergency procedures, antidotes):

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

13. 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.

[any specific national requirements will be listed here]

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

15. OTHER INFORMATION

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

Not all pack sizes may be marketed.

Approved 05 November 2020