

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

### **CARTON**

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

Drontal Plus flavour Bone Shaped Tablets  
Round and Tapewormer

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

Each Drontal Plus Flavour Bone Shaped Tablet contains three active substances: 50 mg praziquantel, 144 mg pyrantel embonate and 150 mg febantel. Each tablet also contains 116.5 mg of artificial beef flavour.

#### **3. PHARMACEUTICAL FORM**

Tablets for dogs.

#### **4. PACKAGE SIZE**

2 tablets for dogs / 1 tablet = 10 kg  
6 tablets for dogs / 1 tablet = 10 kg  
24 tablets for dogs / 1 tablet = 10 kg  
102 tablets for dogs / 1 tablet = 10 kg  
108 tablets for dogs/ 1 tablet = 10 kg

#### **5. TARGET SPECIES**

Dogs

#### **6. INDICATION(S)**

Drontal Plus Flavour Bone Shaped Tablets can be used to treat roundworms and tapeworms commonly found in dogs and puppies in the UK and Ireland.

#### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Give 1 tablet for every 10 kg ( 1 st 8 lb) bodyweight. Adult dogs should be treated every 3 months as a routine measure,

For oral administration only.

**Read the package leaflet before use.**

#### **8. WITHDRAWAL PERIOD**

Not applicable.

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

### **Do not give Drontal Plus Flavour Bone Shaped Tablets:**

- If your dog is receiving other medicines containing piperazine.

Do not exceed the stated dose when treating pregnant bitches. Consult a veterinary surgeon before treating pregnant bitches for roundworm.

### **User warnings**

Always wash your hands after giving your dog Drontal Plus Flavour Bone Shaped Tablets

## **10. EXPIRY DATE**

Expiry date: {month/year}

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C. Dispose of any unused half tablets. Do not keep them for future use. Store in the original packaging. Do not use after the expiry date stated on the foil strip.

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

Dispose of empty packaging and any remaining product in the household refuse.

## **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

*[Distribution category]*

For animal treatment only.

Distribution category: see below

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

Keep out of the reach and sight of children.

## **15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

See below.

## **16. MARKETING AUTHORISATION NUMBER(S)**

See below

## **17. MANUFACTURER’S BATCH NUMBER**

Batch No.: {number}

**Manufactured by:** KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str.  
324, D-24106 Kiel, Germany

UK only

Vm 08007/4167

NFA-VPS

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

IE only

VPA 10021/14/4

CAM

Bayer Ltd  
Animal Health Division  
The Atrium  
Blackthorn Road  
Dublin 18, Ireland  
Tel: 01 299 9313

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**BLISTER STRIP**

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

Drontal Plus flavour Bone Shaped Tablets  
Round and Tapewormer

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Vetoquinol UK Limited logo

**3. EXPIRY DATE**

EXP: {month/year}

**4. BATCH NUMBER**

Batch No.: {number}

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

For animal treatment only.

Ad us. Vet

50 mg Praziquantel  
150 mg Febantel  
144 mg Pyrantel embonate

Contains 2 tablets.

1  = 10 kg 

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

### **DISPENSING ENVELOPE**

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

Drontal Plus flavour Bone Shaped Tablets  
Round and Tapewormer

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

Each Drontal Plus Flavour Bone Shaped Tablet contains three active substances: 50 mg praziquantel, 144 mg pyrantel embonate and 150 mg febantel. Each tablet also contains 116.5 mg of artificial beef flavour.

#### **3. PHARMACEUTICAL FORM**

Tablets for dogs / 1 tablet = 10 kg

#### **4. PACKAGE SIZE**

#### **5. TARGET SPECIES**

Dogs.

#### **6. INDICATION(S)**

Drontal Plus Flavour Bone Shaped Tablets can be used to treat roundworms and tapeworms commonly found in dogs in the UK and Ireland.

#### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

The number of tablets needed to treat your dog depends on your dog's weight. Give 1 tablet for every 10 kg (1 st 8 lb) bodyweight.

The tablet(s) should be given directly to your dog. You can do this either by placing the tablet(s) in the dog's mouth or by hiding it in the dog's food. Adult dogs should be treated every 3 months as a routine measure.

**Read the package leaflet before use.**

#### **8. WITHDRAWAL PERIOD**

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

**Do not give Drontal Plus Flavour Bone Shaped Tablets:**

- If your dog is receiving other medicines containing piperazine.
- Do not exceed the stated dose when treating pregnant bitches. Consult a

veterinary surgeon before treating pregnant bitches for roundworm.

### **User Warnings**

Always wash your hands after giving your dog Drontal Plus Flavour Bone Shaped Tablets.

### **10. EXPIRY DATE**

### **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C. Dispose of any unused half-tablets. Do not keep them for future use. Store in the original packaging. Do not use after the expiry date stated on the foil strip.

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

Dispose of empty packaging and any remaining product in the household refuse.

### **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

*[Distribution category]*

For animal treatment only.

Distribution category, see below.

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

Keep out of the reach and sight of children.

### **15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

See below.

### **16. MARKETING AUTHORISATION NUMBER(S)**

See below

**17. MANUFACTURER'S BATCH NUMBER**

UK only

Vm 08007/4167

NFA-VPS

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

IE only

VPA 10021/14/4

CAM

Bayer Ltd  
Animal Health Division  
The Atrium  
Blackthorn Road  
Dublin 18, Ireland  
Tel: 01 299 9313

Name of Dog:.....

Dog Owner's Name:.....

Address:.....

Supplied by:

[Include information under these headings as it appears in the SPC]

**PACKAGE LEAFLET FOR: DRONTAL PLUS FLAVOUR BONE SHAPED TABLETS FOR DOGS**

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

**UK**

**Marketing Authorisation Holder:**

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

**IE**

**Marketing Authorisation Holder:**

Bayer Limited, Animal Health Division, The Atrium, Blackthorn Road, Dublin 18, Ireland. Tel 01 299 9313

**Manufacturer:**

KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany

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

**The name of this veterinary medicine is:** Drontal Plus Flavour Bone Shaped Tablets.

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

**What is in Drontal Plus Flavour Bone Shaped Tablets:**

Drontal Plus Flavour Bone Shaped Tablets are pale brown to brown, bone shaped tablets, scored on both sides. Each tablet contains three active substances: 50 mg praziquantel, 144 mg pyrantel embonate and 150 mg febantel. Each tablet also contains 116.5 mg artificial beef flavour.

**4. INDICATION(S)**

**What are Drontal Plus Flavour Bone Shaped Tablets used for?**

Drontal Plus Flavour Bone Shaped Tablets can be used to treat roundworms and tapeworms commonly found in dogs in the UK and Ireland. The product is effective against the following types of roundworm and tapeworm: *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*, *Trichuris vulpis*, *Dipylidium caninum*, *Echinococcus* (multiple species) and *Taenia* (multiple species)

Roundworms and tapeworms are parasites that live in the gut. If left untreated they can cause your dog to become unwell. Treating your dog regularly will reduce the risk of other animals and humans being exposed to worm infection.

## **5. CONTRAINDICATIONS**

### **Do not give Drontal Plus Flavour Bone Shaped Tablets:**

- If your dog is receiving other medicines that contain piperazine.

Consult a veterinary surgeon before treating pregnant bitches for roundworm with Drontal Plus Flavour Bone Shaped Tablets. Do not exceed the stated dose when treating pregnant bitches.

## **6. ADVERSE REACTIONS**

### **Possible Side Effects:**

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 non-specific lethargy, anorexia or hyperactivity

If you notice any unexpected effects, please consult your veterinary surgeon.

## **7. TARGET SPECIES**

This veterinary medicine is for use in dogs.

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

### **How often should Drontal Plus Flavour Bone Shaped Tablets be used?**

Adult dogs should be treated every 3 months as a routine measure. If your dog has a heavy infestation of roundworm a repeat dose should be given after 14 days (2 weeks). Puppies should be treated at 2 weeks of age. Treatment should be repeated every 2 weeks until the puppy is 3 months of age. Puppies should then be treated every 3 months as for adult dogs. Not for use in dogs weighing less than 3 kg. Nursing bitches should be treated 2 weeks after giving birth and every 2 weeks until the puppies are weaned. It is advisable to treat the bitch at the same time as the puppies.

### **How many tablets should I give my dog?**

The number of tablets needed to treat your dog depends on your dog's weight. The tablets are scored so they can be broken in half easily. The dose is 1 tablet per 10 kg (1 st 8 lb) bodyweight. Dosages are as follows:

<b>Weight of dog</b>	<b>Dose</b>
<b>Puppies and Small Dogs</b>	
3-5 kg (6 lb 9 oz – 11 lb)	= ½ tablet
6-10 kg (11 lb – 1 st 8 lb)	= 1 tablet
<b>Medium Dogs</b>	
11-15 kg (1 st 10 lb – 2 st 5 lb)	= 1½ tablets
16-20 kg (2 st 7 lb – 3 st 2 lb)	= 2 tablets
21-25 kg (3 st 4 lb – 3 st 13 lb)	= 2½ tablets
26-30 kg (4 st 1 lb – 4 st 10 lb)	= 3 tablets
<b>Large Dogs</b>	
31-35 kg (4 st 12 lb – 5 st 7 lb)	= 3½ tablets
36-40 kg (5 st 9 lb – 6 st 4 lb)	= 4 tablets

## **9. ADVICE ON CORRECT ADMINISTRATION**

### **How do I give Drontal Plus Flavour Bone Shaped Tablets?**

The tablets should be given directly to your dog. You can do this either by placing the tablet(s) in the dog's mouth or by hiding them in the dog's food. No starvation is needed before, or after treatment.

## **10. WITHDRAWAL PERIOD(S)**

## **11. SPECIAL STORAGE PRECAUTIONS**

### **How to store Drontal Plus Flavour Bone Shaped Tablets**

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Dispose of any unused half tablets. Do not keep them for future use.
- Store in the original packaging.
- Do not use after the expiry date stated on the foil strip and outer packaging.

## **12. SPECIAL WARNING(S)**

For Animal Treatment Only.

- Dogs may become infected with worms by eating insects (including fleas and lice), birds, small rodents, rabbits or raw offal from affected sheep, goats and cattle. Dogs will continue to be re-infected unless the route of infection is controlled e.g. treating a flea infestation or preventing a dog from scavenging or hunting.

The product contains praziquantel which is effective against *Echinococcus multilocularis*, a tapeworm which is not present in the UK or Ireland but is becoming more common in some European countries. Infection with *E. multilocularis* can lead to serious even fatal illness in humans. It is recommended that all dogs entering the country, travelling either under the PETS scheme (UK only) or going into quarantine premises (UK & Ireland) should be treated with praziquantel.

## User Warnings

Always wash your hands after giving your dog Drontal Plus Flavour Bone Shaped Tablets.

### 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

#### Disposing of unwanted Drontal Plus Flavour Bone Shaped Tablets

Dispose of empty packaging and any remaining product in the household refuse

### 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

### 15. OTHER INFORMATION

Drontal Plus Flavour Bone Shaped Tablets are available in cartons containing 2, 6, 24, 102 and 108 tablets. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local marketing authorisation holder.

#### UK only

NFA-VPS

Vm 08007/4167

#### IE only

CAM

Companion Animal Medicine

VPA 10021/14/4

Revised: November 2020  
AN: 01025/2020

Approved 05 November 2020

A handwritten signature in black ink, consisting of a stylized, cursive initial followed by the name "Hunter." with a period.