

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

### **CARTON**

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

Drontal Plus Flavour Tablets for Dogs  
Round and Tapewormer

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

One tablet contains 50 mg praziquantel, 144 mg pyrantel embonate and 150 mg febantel as active substances.

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

Flavoured tablets for the control of tapeworms and roundworms of dogs and puppies.

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

2 tablets for dogs / 1 tablet = 10 kg  
8 tablets for dogs / 1 tablet = 10 kg  
24 tablets for dogs / 1 tablet = 10 kg  
104 tablets for dogs / 1 tablet = 10 kg

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

Dogs

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

Read enclosed package leaflet before use.

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

For oral administration only.

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

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

Do not exceed the recommended dose when treating pregnant bitches.  
Consult a veterinary surgeon before treating pregnant bitches for roundworms  
Tapeworm infection is certain to re-occur unless control of intermediate hosts such as fleas, mice etc is undertaken.  
Do not use simultaneously with piperazine compounds.  
Please refer to the package leaflet for disposal advice and user warnings.

## **10. EXPIRY DATE**

Expiry date: {month/year}

## **11. SPECIAL STORAGE CONDITIONS**

Keep blister in outer carton. Do not store above 25°C. Any part-used tablets should be discarded. Do not use this veterinary medicinal product after the expiry date stated on the blister after EXP.

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

Please refer to the package leaflet for disposal advice and user warnings.

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

*[Distribution category]*

Distribution category: see below.

For Animal Treatment Only.

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

KEEP OUT OF 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**

BN: {number}

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

Veterinary Medicinal Product authorised for use in UK and IE.

UK only

Vm 08007/4168

NFA-VPS

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

IE only

VPA 10021/060/001

CAM

Bayer Ltd  
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 Tablets for Dogs

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

Vetoquinol UK Limited logo

**3. EXPIRY DATE**

Expiry Date: {month/year}

EXP: {month/year}

**4. BATCH NUMBER**

BN: {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

1  = 10 kg 

Contains 2 tablets.

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

**PACKAGE LEAFLET FOR: DRONTAL PLUS FLAVOUR 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**

Drontal Plus Flavour Tablets for Dogs  
Round and Tapewormer

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

Flavoured tablets for the control of tapeworms and roundworms of dogs and puppies.

**Description**

Light brown to brown round flat tablet, cross scored on one side. 1 tablet contains 50 mg praziquantel, 144 mg pyrantel embonate, 150 mg febantel and 116.5 mg artificial beef flavour irradiated.

**4. INDICATION(S)**

**Worms controlled include:**

**Ascarids:** *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).

**Hookworms:** *Uncinaria stenocephala*, *Ancylostoma caninum* (adults)

**Whipworms:** *Trichuris vulpis* (adults)

**Tapeworms:** *Echinococcus* spp. *Taenia* spp. and *Dipylidium* species  
(adult and immature forms).

## 5. CONTRAINDICATIONS

Not for use in dogs weighing less than 3 kg.

## 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 lethargy, anorexia or hyperactivity.

## 7. TARGET SPECIES

Dogs.

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

### Dosage

1 tablet per 10 kg (22 lbs) bodyweight. The tablet can be given directly to the dog or disguised in food. No starvation is needed before, or after, treatment.

#### Puppies and Small Dogs:

3-5 kg bodyweight	= ½ tablet
>5-10 kg bodyweight	= 1 tablet

#### Medium Dogs:

>10-15 kg bodyweight	= 1½ tablets
>15-20 kg bodyweight	= 2 tablets
>20-25 kg bodyweight	= 2½ tablets
>25-30 kg bodyweight	= 3 tablets

#### Large Dogs:

>30-35 kg bodyweight	= 3½ tablets
>35-40 kg bodyweight	= 4 tablets

## 9. ADVICE ON CORRECT ADMINISTRATION

For the control of *Toxocara*, nursing bitches should be dosed 2 weeks after giving birth and every two weeks until weaning. Puppies should be treated at 2 weeks of

age and every 2 weeks until 12 weeks of age. Thereafter, they should be treated at 3 month intervals. It is advisable to treat the bitch at the same time as the puppies.

For routine control, adult dogs should be treated every 3 months. In the event of heavy roundworm infection, a repeat dose should be given after 14 days.

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

#### **11. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C. Keep blister in outer carton. Part used tablets should be discarded. Do not use this veterinary medicinal product after the expiry date stated on the blister after EXP.

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

For Animal Treatment Only. .

Do not exceed recommended dose when treating pregnant bitches.

Consult a veterinary surgeon before treating pregnant bitches for roundworms.

Do not use simultaneously with piperazine compounds.

Concurrent use with other cholinergic compounds is not recommended.

Tapeworm infection is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

#### **User warnings**

In case of accidental ingestion, seek medical advice and show the package leaflet to the physician.

In the interests of good hygiene, persons administering the tablets directly to a dog, or by adding them to the dog's food, should wash their hands afterwards.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

November 2020

## 15. OTHER INFORMATION

Since it contains praziquantel, the product is effective against *Echinococcus multilocularis* which does not occur in the UK or Ireland but is becoming more common in some European countries. As a precautionary measure to prevent establishment of *E. multilocularis* in the UK and Ireland, it is recommended that all dogs entering the country be treated with praziquantel.

Drontal Plus Flavour Tablets for Dogs are available in cartons containing 2, 8, 24 and 104 tablets. Not all pack sizes may be marketed.

Veterinary Medicinal Product authorised for use in UK and Ireland.

### UK only

NFA-VPS

Vm 08007/4168

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

### IE only

CAM

Companion Animal Medicine

VPA 10021/060/001

Bayer Ltd  
The Atrium  
Blackthorn Road  
Dublin 18  
Tel 01 299 9313

### **Manufactured by:**

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



Revised: November 2020  
AN: 01025/2020

Approved 05 November 2020

A handwritten signature in black ink, appearing to read "Hunter." with a stylized initial.