

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

### **CARTON**

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

Drontal Plus XL Flavour Tablets for Dogs  
Round and Tapewormer

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

One tablet contains 175 mg praziquantel, 504 mg pyrantel embonate, 525 mg febantel and 408 mg artificial beef flavour irradiated.

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

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

2 tablets for dogs / 1 tablet = 35 kg  
8 tablets for dogs / 1 tablet = 35 kg  
48 tablets for dogs / 1 tablet = 35 kg  
96 tablets for dogs / 1 tablet = 35 kg

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

Dogs

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

For the control of tapeworms and roundworms of adult dogs.

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

For oral administration only.  
Read enclosed leaflet before use. The recommended dose is 1 tablet per 35 kg bodyweight.

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

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

Do not exceed the stated dose when treating pregnant bitches.

Consult a veterinary surgeon before treating pregnant bitches for roundworms.  
Do not use simultaneously with piperazine compounds.

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

## **10. EXPIRY DATE**

Expiry: {month/year}

## **11. SPECIAL STORAGE CONDITIONS**

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. Keep blister in outer carton.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

## **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 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

Veterinary Medicinal Product authorised for use in UK and IE.

UK only

Vm 08007/4169

NFA-VPS

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

IE only

VPA 10021/55/1

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 XL Flavour Tablets for Dogs

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

Vetoquinol UK Limited logo

#### 3. EXPIRY DATE

Expiry: {month/year}

Expiry date: {month/year}

#### 4. BATCH NUMBER

Batch No.: {number}

#### 5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Ad us. vet

175 mg Praziquantel  
504 mg Pyrantel embonate  
525 mg Febantel



Contains 2 tablets

Keep out of reach of children

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**DISPENSING ENVELOPE**

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

Drontal Plus XL Flavour Tablets for Dogs  
Round and Tapewormer

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

1 tablet contains 175 mg praziquantel, 504 mg pyrantel embonate, 525 mg febantel and 408 mg artificial beef flavour irradiated.

**3. PHARMACEUTICAL FORM**

Tablets for dogs / 1 tablet = 35 kg

**4. PACKAGE SIZE**

**5. TARGET SPECIES**

Dogs.

**6. INDICATION(S)**

For the control of tapeworms and roundworms of adult dogs.

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

For oral administration only.

Read enclosed leaflet before use.

The recommended dose is 1 tablet per 35 kg body weight.

**8. WITHDRAWAL PERIOD**

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

Do not exceed stated dose when treating pregnant bitches.

Consult a veterinary surgeon before treating pregnant bitches for roundworm.

Do not use simultaneously with piperazine compounds.

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

**10. EXPIRY DATE**

## **11. SPECIAL STORAGE CONDITIONS**

Keep blister in outer carton. Any part-used tablets should be discarded.

Do not store above 25°C. 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**

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulatory authority.

## **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.

Veterinary Medicinal Product authorised for use in the UK and IE.

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

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

UK only

Vm 08007/4169

NFA-VPS

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

IE only

VPA 10021/55/1

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:.....

Date: .....Give:  tablets

Supplied by:

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

**PACKAGE LEAFLET FOR: DRONTAL PLUS XL 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 XL Flavour Tablets for Dogs  
Round and Tapewormer

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

Flavoured tablets for the control of gastrointestinal tapeworms and roundworms of adult dogs.

**Description**

Pale brown to brown oval shaped divisible tablet scored on both sides. 1 tablet contains 175 mg praziquantel, 504 mg pyrantel embonate, 525 mg febantel and 408 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 caninum* (adult and immature forms).

## 5. CONTRAINDICATIONS

Do not exceed stated dose when treating pregnant bitches.

Do not use simultaneously with piperazine compounds. Concurrent use with other cholinergic compounds is not recommended.

## 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 may be accompanied by nonspecific signs such as lethargy, anorexia or hyperactivity.

## 7. TARGET SPECIES

Dogs.

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

### Dosage

For oral administration only.

### Dosages are as follows

Bodyweight (kg)	Table Quantity
17.5	½
>17.5 – 35	1
>35 – 52.5	1½
>52.5 – 70	2

Drontal Plus Flavour Tablets should be used to achieve accurate dosing in dogs weighing less than 17.5 kg. The dose is equivalent to 1 tablet per 10 kg.

## 9. ADVICE ON CORRECT ADMINISTRATION

The tablet(s) can be given directly to the dog or disguised in food. No starvation is needed before, or after, treatment.

For routine treatment, a single dose is recommended.

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

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

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

## **11. SPECIAL STORAGE PRECAUTIONS**

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

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

For animal treatment only.

Consult a veterinary surgeon before treating pregnant bitches for roundworms. Drontal Plus XL Flavour Tablets may be used during lactation.

Tapeworm infestation 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.

Drontal Plus XL Flavour Tablets are well tolerated in dogs. In safety studies doses of 5 x or greater gave rise to occasional vomiting.

**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

Dosage packs containing 2, 8, 48 or 96 tablets, blister packed in foil strips are available. Not all pack sizes may be marketed.

Veterinary Medicinal Product authorised for use in the UK and IE.

UK only

NFA-VPS

Vm 08007/4169

IE only

CAM

Companion Animal Medicine

VPA 10021/55/1

Approved 05 November 2020

