

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Drontal Tablets Cats Veterinary

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<b>Active Constituents</b>	<b>mg per tablet</b>
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Pyrantel Embonate	230.0
Praziquantel	20.0

#### **Relevant Constituents of the Excipients**

Titanium Dioxide	1.8 mg
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For full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Film-coated tablet.

White to yellowish scored coated tablet. The tablet can be divided into equal halves.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cats

#### **4.2 Indications for use, specifying the target species**

For the treatment of tapeworms and roundworms in cats.

#### **4.3 Contraindications**

Do not use simultaneously with piperazine compounds.  
Not intended for use in kittens less than 6 weeks of age.  
Do not use during pregnancy.

#### **4.4 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.

#### **4.5 Special precautions for use**

- i. Special precautions for use in animals

None.

- ii. Special precautions to be taken by the person administering the medicinal product to animals

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

#### **4.6 Adverse reactions (frequency and seriousness)**

Mild and transient digestive tract disorders such as hypersalivation and/or vomiting and mild and transient neurological disorders such as ataxia may occur in extremely rare cases.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

<https://sideeffects.health.gov.il/>

Adverse events can also be reported to Lidorr Elements, by email to: [lidorvet@lidorr.com](mailto:lidorvet@lidorr.com)

#### **4.7 Use during pregnancy and lactation**

Not to be used during pregnancy but may be used during lactation.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

Do not use simultaneously with piperazine compounds.

#### **4.9 Amount(s) to be administered and administration route**

*Dosage*

1 tablet per 4 kg bodyweight according to the below:

<u>The cat's weight</u>	<u>Number of tablets to administer:</u>
2 kg bodyweight	½ tablet
4 kg bodyweight	1 tablet
6 kg bodyweight	1 ½ tablets
8 kg bodyweight	2 tablets

*Administration and Duration of Treatment*

Single oral administration. The tablet should be given directly to the animal, but if necessary can be disguised in food.

#### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No information.

#### 4.11 Withdrawal period(s)

Not applicable.

### 5. PHARMACOLOGICAL PROPERTIES

An anthelmintic active against gastrointestinal roundworms and tapeworms. The product contains two active ingredients:

1. Pyrantel embonate (pamoate) a tetrahydropyrimidine derivative and
2. Praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative

**ATC VetCode:** QP52 AA51

**Pharmacotherapeutic Group:** Anthelmintics, Praziquantel combinations.

#### 5.1 Pharmacodynamic properties

Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis and thereby allow expulsion from the gastrointestinal (GI) system by peristalsis.

Praziquantel is very rapidly absorbed into and distributed throughout the parasite. Both in vivo and in vitro studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.

In this fixed combination product pyrantel is active against the following ascarids: *Toxocara cati* and *Toxascaris leonina*. Praziquantel is effective against tapeworms in particular *Dipylidium caninum* and *Taenia taeniaeformis*.

The product has also been shown to be efficacious in the control of hookworms, *Ancylostoma tubaeforme* and *A. braziliense* and the tapeworm *Joyeuxiella pasqualei*. Since it contains praziquantel, the product is effective against *Echinococcus multilocularis*, which becoming more common in some European countries.

#### 5.2 Pharmacokinetic properties

No data available.

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Maize starch, Microcrystalline cellulose, Polyvidone, Methylhydroxypropylcellulose, Polyethylene glycol 4000, Titanium dioxide, Magnesium stearate, Colloidal anhydrous silica.

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf-life**

The expiry date of the product is indicated on the packaging materials.

## **6.4 Special precautions for storage**

Store below 25°C.

Do not remove tablets from strip packaging until required for use.

Any part used tablets should be discarded.

## **6.5 Nature and composition of immediate packaging**

Container material:	Aluminium foil blister of polyethylene coated aluminium blister
Closure:	Heat seal
Container colour:	Silver or white coloured
Container sizes:	Cartons containing 2, 4, 6, 8, 20, 24, 96, 100 or 144 tablets.

Not all pack sizes may be marketed.

## **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

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

## **7. MANUFACTURER**

Bayer Animal Health GmbH  
D-51368 LEVERKUSEN, GERMANY

## **8. REGISTRATION HOLDER**

Lidorr Elements Ltd.  
63 HaNevi'im st., Ind.Area Morasha, Ramat HaSharon.

## **8. REGISTRATION NUMBER**

083-22-92224-00

**9. Revised in**

December 2020