

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

**{CARTON FOR PACK SIZES OF 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42 AND 44 TABLETS AND ABOVE}**

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

Prazitel 230/20 mg Flavoured Film-Coated Tablets

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

Each film-coated tablet contains Pyrantel embonate 230 mg and Praziquantel 20 mg.

### **3. PACKAGE SIZE**

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 128, 136, 140, 144, 150, 152, 160, 168, 176, 180, 184, 192, 200, 204, 206, 208, 216, 224, 232, 240, 248, 250, 280, 300, 500 or 1000 tablets

### **4. TARGET SPECIES**

Cats.

### **5. INDICATION(S)**

For veterinary medicinal products not subject to veterinary prescription:

For the treatment of mixed infections caused by gastrointestinal roundworms and tapeworms.

### **6. ROUTES OF ADMINISTRATION**

Oral use.

1 tablet per 4 kg bodyweight.

### **7. WITHDRAWAL PERIODS**

### **8. EXPIRY DATE**

Exp. {mm/yyyy}

Unused half tablets must be discarded.

## **9. SPECIAL STORAGE PRECAUTIONS**

### **10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

### **11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

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

Keep out of the sight and reach of children.

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

Chanelle Pharmaceuticals Manufacturing Ltd.

### **14. MARKETING AUTHORISATION NUMBERS**

Vm 08749/5054

### **15. BATCH NUMBER**

Lot {number}

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

Read the package leaflet before use.

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

Disposal: Read package leaflet

### **18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

NFA-VPS

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Blisters}**

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

Prazitel 

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)**

Each film-coated tablet contains Pyrantel embonate 230 mg and Praziquantel 20 mg.

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Unused half tablets must be discarded.

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

For animal treatment only.

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

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

Prazitel 230/20 mg Flavoured Film-Coated Tablets for Cats

### **2. COMPOSITION**

Each film-coated tablet contains Pyrantel embonate 230 mg and Praziquantel 20 mg.

A white to off white round, biconvex coated tablet with a break line on one side and plain on the other side.

The tablet can be divided into two equal parts.

### **3. TARGET SPECIES**

Cats

### **4. INDICATIONS FOR USE**

For the treatment of mixed infections caused by the following gastrointestinal roundworms and tapeworms:

**Roundworms:** *Toxocara cati*, *Toxascaris leonina*.

**Tapeworms:** *Dipylidium caninum*, *Taenia taeniaeformis*, *Echinococcus multilocularis*.

### **5. CONTRAINDICATIONS**

Do not use in kittens less than 6 weeks of age.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

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

**Special warnings:**

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.

If there is a risk for re-infestation the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration in cats. Local epidemiological information and the living conditions of the cat should be taken into account. It is also important to remove sources of possible re-infestation such as fleas and mice.

Parasitic resistance to a certain class of anthelmintics can occur after frequent and repeated use of an anthelmintic from this class.

Special precautions for safe use in the target species:

As the tablets are flavoured, they should be stored in a safe place out of the reach of animals. Animals in a poor condition or heavily infested, which can be manifested by symptoms such as diarrhoea, vomiting, presence of parasites in faeces and vomit, poor hair condition, should be examined by a veterinarian prior to the veterinary medicinal product administration. For severely debilitated or heavily infested cats, use only according to a benefit/risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In the interests of good hygiene, persons administering the tablets directly to the cat, or by adding them to the cat's food, should wash their hands afterwards. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (WOAH), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

Pregnancy and lactation:

Do not use during pregnancy.  
Can be used during lactation.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with piperazine compounds.

Overdose:

After doses higher than 5 times the recommended dose, signs of intolerance such as vomiting have been observed.

## 7. ADVERSE EVENTS

Cats.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Digestive tract disorders (e.g., vomiting and/or hypersalivation). Neurological disorders (e.g., ataxia and muscle tremors).

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

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

Oral use.

### *Dosage*

The recommended dose is: 20 mg/kg pyrantel (57.5 mg/kg pyrantel embonate) and 5 mg/kg praziquantel in a single administration. This is equivalent to 1 tablet per 4 kg bodyweight.

Body weight	Tablets
1.0 - 2.0 kg.	½
2.1 - 4.0 kg.	1
4.1 - 6.0 kg.	1 ½
6.1 - 8.0 kg.	2

The tablet should be given directly to the cat, but if necessary, can be disguised in food.

In ascarid infestation, especially in kittens, complete elimination cannot be expected, so a risk of infection for humans can persist. Repeat treatments should, therefore, be carried out with a suitable roundworm veterinary medicinal product at 14 day intervals until 2-3 weeks after weaning. If signs of disease persist or appear, consult a veterinary surgeon.

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

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

N/A

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Unused half tablets must be discarded.

Keep the blister in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after Exp. The expiry date refers to the last day of that month.

This veterinary medicinal product does not require any special storage conditions.

## **12. SPECIAL PRECAUTIONS FOR DISPOSAL**

Medicines should not be disposed of via wastewater.

Dispose of waste material in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

## **13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product not subject to prescription

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 08749/5054

Individual blisters made up of a PVC/PE/PCTFE white opaque copolymer and a 20 µm heatseal lacquer/aluminium containing 2, 4, 6, 8, 10, 12, 14, 16, 18 or 20 tablets.

or

Individual blisters made up of 45 µm PVC/aluminium/orientated polyamide and a 20 µm heatseal lacquer/aluminium containing 2 or 8 tablets.

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 64, 68, 70, 72, 76, 80, 84, 88, 92, 96, 98, 100, 104, 106, 108, 112, 116, 120, 128, 136, 140, 144, 150, 152, 160, 168, 176, 180, 184, 192, 200, 204, 206, 208, 216, 224, 232, 240, 248, 250, 280, 300, 500 or 1000 tablets.

Not all pack sizes may be marketed.

## 15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

September 2023

*Find more product information by searching for the 'Product Information Database' or 'PID' on [www.gov.uk](http://www.gov.uk)*

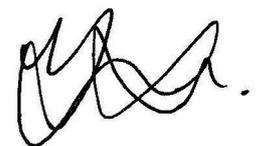
## 16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd.  
Loughrea  
Co. Galway  
Ireland

Local representatives and contact details to report suspected adverse reactions:

Chanelle Animal Health,  
7 Rodney Street,  
Liverpool L1 9HZ,  
UK  
Telephone: +353 (0) 91 841788  
[vetpharmacoviggroup@chanellegroup.ie](mailto:vetpharmacoviggroup@chanellegroup.ie)



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