

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**{CARTON FOR PACK SIZES OF 2,4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42 ,44, 48 TABLETS, AND UPWARDS }**

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

Cazitel Plus XL Tablets For Dogs

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains 175 mg Praziquantel, 504 mg Pyrantel Embonate (equivalent to 175 mg Pyrantel) and 525 mg Febantel .

**3. PACKAGE SIZE**

- 2 tablets
- 4 tablets
- 5 tablets
- 6 tablets
- 8 tablets
- 10 tablets
- 12 tablets
- 14 tablets
- 16 tablets
- 18 tablets
- 20 tablets
- 24 tablets
- 28 tablets
- 30 tablets
- 32 tablets
- 36 tablets
- 40 tablet
- 42 tablets
- 44 tablets
- 48 tablets
- 50 tablets
- 52 tablets
- 56 tablets
- 60 tablets

- 64 tablets
- 68 tablets
- 70 tablets
- 72 tablets
- 76 tablets
- 80 tablets
- 84 tablets
- 88 tablets
- 92 tablets
- 96 tablets
- 98 tablets
- 100 tablets
- 104 tablets
- 106 tablets
- 108 tablets
- 112 tablets
- 116 tablets
- 120 tablets
- 140 tablets
- 150 tablets
- 180 tablets
- 200 tablets
- 204 tablets
- 206 tablets
- 208 tablets
- 250 tablets
- 280 tablets
- 300 tablets
- 500 tablets
- 1000 tablets

**4. TARGET SPECIES**

Dogs.

## **5. INDICATIONS**

For products not subject to veterinary prescription .

Treatment of mixed infections by nematodes and cestodes.

## **6. ROUTES OF ADMINISTRATION**

Oral use.

1 tablet per 35 kg bodyweight.

The tablets can be given directly to the dog or disguised in food.

## **7. WITHDRAWAL PERIODS**

## **8. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf-life of half tablets: 14 days

## **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 OF THE MARKETING AUTHORISATION HOLDER**

Chanelle Pharmaceuticals Manufacturing Ltd.,  
Loughrea  
Co. Galway  
Ireland

**14. MARKETING AUTHORISATION NUMBERS**

Vm 08749/3003

**15. BATCH NUMBER**

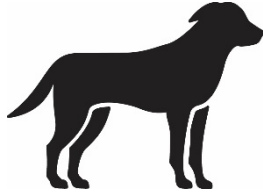
Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

{BLISTER FOIL TEXT}

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

Cazitel Plus XL



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Each tablet contains 175 mg Praziquantel, 504 mg Pyrantel Embonate (equivalent to 175 mg Pyrantel) and 525 mg Febantel.

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

## **B. PACKAGE LEAFLET**



## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Cazitel Plus XL Tablets For Dogs

### 2. Composition

Each pork flavoured tablet contains 175 mg Praziquantel, 504 mg Pyrantel Embonate (equivalent to 175 mg pyrantel) and 525 mg Febantel.

A yellow coloured oblong tablet with a breakline on both sides.  
The tablets can be divided into two equal parts.

### 3. Target species

Dogs

### 4. Indications for use

In adult dogs: Treatment of mixed infections by nematodes and cestodes of the following species

#### **Nematodes:**

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

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

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

#### **Cestodes:**

**Tapeworms:** *Echinococcus* species, (*E. granulosus*, *E. multilocularis*), *Taenia* species,

(*T. hydatigena*, *T. pisiformis*, *T. taeniformis*) *Dipylidium caninum* (adult and immature forms).

### 5. Contraindications

Do not use simultaneously with piperazine compounds.

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

### 6. Special warnings

#### 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.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product.

Special precautions for safe use in the target species:

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

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

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

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

For animal treatment only.

Pregnancy:

Teratogenic effects attributed to high doses of febantel have been reported in sheep and rats. No studies have been performed in dogs during early pregnancy. Use of the product during pregnancy should be in accordance with a benefit risk assessment by the responsible veterinarian. The use is not recommended during the first 4 weeks of pregnancy in dogs. Do not exceed the stated dose when treating pregnant bitches.

Interactions with other medicinal products and other forms of interaction:

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.

Concurrent use with other cholinergic compounds can lead to toxicity.

Overdose:

The combination of praziquantel, pyrantel embonate and febantel is well tolerated in dogs. In safety studies, a single dose of 5 times the recommended dose or greater gave rise to occasional vomiting.

Other precautions:

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

## 7. Adverse events

Dogs:

Very rare
(<1 animal / 10,000 animals treated, including isolated reports):
Digestive tract disorders (diarrhoea, emesis)

Reporting adverse events is important. It allows continuous safety monitoring of a 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, routes and method of administration

Oral use.

The recommended dose rates are: 15 mg/kg bodyweight febantel, 5 mg/kg pyrantel (equivalent to 14.4 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. This is equivalent to 1 Cazitel Plus XL tablet per 35 kg. bodyweight.

Dogs of > 35 kg. bodyweight should be given 1 Cazitel Plus XL tablet plus the appropriate quantity of Cazitel Plus tablets equivalent to 1 tablet per 10 kg. bodyweight.

Dogs weighing approximately 17.5 kg. bodyweight should be given ½ Cazitel Plus XL tablet.

The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

Dosage table:

<b>Bodyweight (kg)</b>	<b>Tablets</b>
Approximately 17.5 kg.	½ Cazitel Plus XL tablet
31-35 kg.	1 Cazitel Plus XL tablet
36-40 kg.	1 Cazitel Plus XL tablet plus ½ Cazitel Plus tablet
41-45 kg.	1 Cazitel Plus XL tablet plus 1 Cazitel Plus tablet
46-50 kg.	1 Cazitel Plus XL tablet plus 1½ Cazitel Plus tablets
51-55 kg.	1 Cazitel Plus XL tablet plus 2 Cazitel Plus tablets
56-60 kg.	1 Cazitel Plus XL tablet plus 2½ Cazitel Plus tablets
61-65 kg.	1 Cazitel Plus XL tablet plus 3 Cazitel Plus tablets
66-70 kg.	2 Cazitel Plus XL tablets

The tablets can be divided into two equal parts

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.

#### **9. Advise on correct administration**

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

#### **10. Withdrawal periods**

Not Applicable.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

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

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

Shelf-life of half tablets: 14 days

Each time an unused half tablet is stored, it should be returned to the open blister space and the blister inserted back into the outer carton.

#### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems.

These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

### **13. Classification of veterinary medicinal products**

BE, BG, CZ, EE, FI, HU, IE, IT, LV, LT, NL, RO, SK, SI, UK: Veterinary medicinal product not subject to prescription.

AT, CY, DE, EL, LU, PL, PT, ES: Veterinary medicinal product subject to prescription.

SE: Veterinary medicinal product subject to veterinary prescription except for some pack sizes.

### **14. Marketing authorisation numbers and pack sizes**

2, 4, 5, 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, 140, 150, 180, 200, 204, 206, 208, 250, 280, 300, 500 or 1000 tablets.

Not all pack sizes may be marketed.

### **15. Date on which the package leaflet was last revised**

Detailed information on this veterinary medicinal product is available in the Union Product Database.

<https://upd-portal-prod.azurewebsites.net/updwebui/home>

### **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Chanelle Pharmaceuticals Manufacturing Ltd.,  
Loughrea,  
Co. Galway.  
Ireland

Telephone: +353 (0)91 841788

[vetpharmacoviggroup@chanellegroup.ie](mailto:vetpharmacoviggroup@chanellegroup.ie)

Local representatives and contact details to report suspected adverse reactions:

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

Approved 08 June 2023

A handwritten signature in black ink, appearing to be a stylized name or set of initials.