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

Prazitel 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 tablets
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 08749/3006

15. BATCH NUMBER

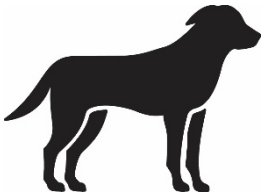
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER FOIL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prazitel 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

Prazitel 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 Prazitel Plus XL tablet per 35 kg. bodyweight.
Dogs of > 35 kg. bodyweight should be given 1 Prazitel Plus XL tablet plus the appropriate quantity of Prazitel Plus tablets equivalent to 1 tablet per 10 kg. bodyweight.
Dogs weighing approximately 17.5 kg. bodyweight should be given ½ Prazitel 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:

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

June 2023

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

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