ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON FOR PACK SIZES OF 2, 4, 6 AND 8 TABLETS AND UPWARDS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prazitel Plus Tablets for Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains Praziquantel 50 mg, Pyrantel 50 mg (equivalent to 144 mg Pyrantel Embonate) and Febantel 150 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, 70, 80, 84, 90, 98, 100, 104, 106, 120, 140, 150, 180, 200, 204, 206, 250, 280, 300, 500 and 1000 tablets.

4. TARGET SPECIES

Dogs.

5. INDICATIONS

For veterinary medicinal products not subject to veterinary prescription:
Treatment of mixed infections by nematodes and cestodes.

6. ROUTES OF ADMINISTRATION

Oral use.
1 tablet per 10 kg bodyweight.
The tablets can be given directly to the dog or disguised in food.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Discard any unused divided tablets immediately.

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.

14. MARKETING AUTHORISATION NUMBER

Vm 08749/3019

15. BATCH NUMBER

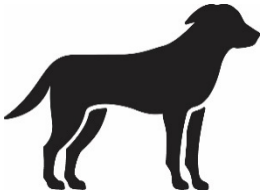
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BLISTER FOIL TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prazitel Plus Tablets for Dogs



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains Praziquantel 50 mg, Pyrantel 50 mg (equivalent to 144 mg Pyrantel Embonate) and Febantel 150 mg.

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 Tablets For Dogs

2. Composition

Each tablet contains Praziquantel 50 mg, Pyrantel 50 mg (equivalent to 144 mg Pyrantel Embonate) and Febantel 150 mg.
A pale yellow tablet with a cross breakline on one side.
The tablets can be divided into 2 or 4 equal parts.

3. Target species

Dogs.

4. Indications for use

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 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 re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice immediately 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.

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:
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 veterinary medicinal 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.

Interaction 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 antagonised. Concurrent use with other cholinergic compounds (e.g. foxim) 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.

7. Adverse events

Dogs:

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

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: {national system details}

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 in a single dose.
1 tablet per 10 kg bodyweight. The tablets can be given directly to the dog or disguised in food. No starvation is needed before, or after, treatment.
The tablet can be divided in two or four equal doses.

Dosage table:

Bodyweight (kg)	Tablets
0.5 - 2.5	¼
2.6-5.0	½
5.1-10.0	1
10.1-15.0	1½
15.1-20.0	2
20.1-25.0	2½
25.1-30.0	3
30.1-35.0	3½
35.1-40.0	4
>40.1	1 tablet per 10 kg

The advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

9. Advice on correct administration

To ensure administration of a correct dose, 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 storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Discard any unused divided tablets immediately.

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

PL, SL, DK, HU, AU, ES, PT, LT, LV, DE, CZ, EL, IS: Veterinary medicinal product subject to prescription.
RO, SK, LU, IE, EE, FI, UK (NI), IT, NL: Veterinary medicinal product not subject to prescription.

14. Marketing authorisation number and pack sizes

Vm 08749/3019

Strips or blisters packed into cartons containing either 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 70, 80, 84, 50, 52, 56, 60, 70, 80, 84, 90, 98, 100, 104, 106, 120, 140, 150, 180, 200, 204, 206, 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

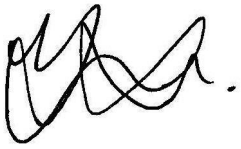
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

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@chanellegoup.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: 12 February 2024