SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prazitel Plus Tablets For Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substances:

Praziquantel	50 mg
Pyrantel (equivalent to 144 mg pyrantel embonate)	50 mg
Febantel	150 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
A pale yellow tablet with a cross breakline on one side.
The tablets can be divided into 2 or 4 equal parts

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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).

4.3 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.

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 reoccur 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.

4.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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 the dog, or by adding them to the dog's food, should wash their hands afterwards.

Special precautions for the protection of the environment:

Not applicable.

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.

4.6 Adverse reactions (frequency and seriousness)

Dogs:

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national

competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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 can lead to toxicity.

4.9 Amount(s) to be administered and administration route

Oral use.

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

The recommended dose rates are: 15mg/kg bodyweight febantel, 5 mg/kg pyrantel (equivalent to 14.4 mg/kg pyrantel embonate) and 5 mg/kg praziquantel in a single dose. This is equivalent to 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 advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

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

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacotherapeutic group:

ATC Vet Code: QP52AA51

5.2 Pharmacodynamic properties

This veterinary medicine product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The veterinary medicine product contains three active substances, as follows:
Febantel, a probenzimidazole

Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative

Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative

In this fixed combination, pyrantel and febantel act against all relevant nematodes (ascarids, hookworms, and whipworms) in dogs. In particular, the activity spectrum covers *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum* and *Trichuris vulpis*. This combination shows synergistic activity in the case of hookworms and febantel is effective against *T. vulpis*.

The spectrum of activity of praziquantel covers all important cestode species in dogs, in particular *Taenia* spp., *Dipylidium caninum*, *Echinococcus granulosus* and *Echinococcus multilocularis*. Praziquantel acts against all adult and immature forms of these parasites.

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

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

Within the mammalian system, febantel undergoes ring closure, forming fenbendazole and oxfendazole. It is these chemical entities which exert the anthelmintic effect by inhibition of tubulin polymerisation. Formation of microtubules is thereby prevented, resulting in disruption of structures vital to the normal functioning of the helminth. Glucose uptake in particular is affected, leading to a depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2 – 3 days later. 5.2 Pharmacokinetic particulars

6. PHARMACEUTICAL PARTICULARS

Perorally administered praziquantel is absorbed almost completely from the intestinal tract. After absorption, the drug is distributed to all organs. Praziquantel is metabolized into inactive forms in the liver and secreted in bile. It is excreted within 24 hours to more than 95% of the administered dosage. Only traces of non-metabolised praziquantel are excreted.

Following administration of the veterinary medicine to dogs, peak plasma concentrations of praziquantel were achieved by approximately 2.5 hours.

The pamoate salt of pyrantel has low aqueous solubility, an attribute that reduces absorption from the gut and allows the drug to reach and be effective against parasites in the large intestine. Following absorption, pyrantel pamoate is quickly and almost completely metabolized into inactive metabolites that are excreted rapidly in the urine.

Febantel is absorbed relatively rapidly and metabolized to a number of metabolites including fenbendazole and oxfendazole, which have anthelmintic activity.

Following administration of the veterinary medicine product to dogs, peak plasma concentrations of fenbendazole and oxfendazole were achieved by approximately 7-9 hours.

6.1 List of excipients

Lactose monohydrate,
Microcrystalline cellulose,
Magnesium stearate,
Colloidal anhydrous silica,
Croscarmellose sodium,
Sodium laurilsulfate
Pork flavour

6.2 Major Incompatibilities

Not applicable

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years
Discard any unused divided tablets immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is presented in either:

Individual strips composed of aluminium foil 30 µm/30 gsm extruded polythene, containing 2, 4, 6, 8, 10, 12, 14, 16, 18 or 20 tablets.
or

Individual blisters composed of 45 µm, soft temper aluminium foil and 25 µm hard temper aluminium foil, containing 2 or 8 tablets.

The strips or blisters are 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, 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 08749/5055

9. DATE OF FIRST AUTHORISATION

15 December 2009

10. DATE OF REVISION OF THE TEXT

July 2025

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

NFA-VPS- Veterinary medicinal product not subject to prescription.

Gavin Hall

Approved: 31 July 2025