CONSUMER PACKAGE INSERT FOR A VETERINARY PREPARATION

The medicine is dispensed with a veterinarian's prescription only

For animal treatment only

1. NAME OF THE VETERINARY MEDICINE, ITS FORM AND STRENGTH

Prazitel Plus Veterinary Tablets

2. ACTIVE INGREDIENTS

Each tablet contains:

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

Inactive and allergenic ingredients: see section 13 "Further information".

3. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of nematodes and cestodes in dogs, 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).

Therapeutic group:

Anthelmintic.

4. CONTRAINDICATIONS

Do not use the product simultaneously with preparations containing piperazine as the anthelmintic activity of pyrantel and piperazine may be contraindicated.

Do not use the product in animals with a known sensitivity to the active ingredients or to any of the inactive ingredients.

5. SIDE EFFECTS

In very rare cases, gastrointestinal disturbances (diarrhea, vomiting) have been observed.

If you notice any serious adverse reactions not mentioned in this leaflet, please inform your veterinarian.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link:

http://sideeffects.health.gov.il

6. TARGET SPECIES

Dogs

7. MODE OF ADMINISTRATION AND DOSAGE

Single dose: For oral administration.

The recommended dosage are: 15 mg/kg bodyweight febantel, 5 mg/kg pyrantel (equivalent to approximately 14.4 mg/kg pyrantel embonate) and 5 mg/kg praziquantel.

One Prazitel Plus tablet per 10 kg bodyweight. The tablets can be given directly to the dog or mixed with food. The dog does not have to be fasting before or after treatment.

The tablet can be divided into two or four equal doses.

Dosage table:

Bodyweight (kg)	Tablets
½-2.5	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 of the medicine.

8. HOW TO USE THE PRODUCT

To ensure administration of a correct dose, body weight should be determined as accurately as possible. The tablets can be split into two or four equal parts.

9. WITHDRAWAL PERIOD

Not applicable.

10. WARNINGS

- Special warnings regarding use in target species

  Do not use the product concomitantly with products containing piperazine, as the anthelmintic effects of pyrantel and piperazine may be contraindicated. Concurrent use with other cholinergic products can lead to toxicity.

  If you are uncertain, and your dog is given other veterinary medicinal products, check with a veterinarian or pharmacist.

  Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation is certain to re-occur if no action is taken against their intermediate hosts, such as fleas, mice and the like.

  Tapeworm infestation is unlikely in pups less than 6 weeks of age.

  Teratogenic effects attributed to high dosages 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. It is recommended that the product not be used in dogs during the first 4 weeks of pregnancy. Do not exceed the stated dosage when treating pregnant dogs.

  Parasites may develop resistance to a particular class of anthelmintics following frequent and repeated use of an anthelmintic of that class.

- Special safety-related warnings for the person handling the product

  In case of accidental ingestion, seek medical assistance and show the package leaflet 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.

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  Echinococcosis represents a hazard for humans. As echinococcosis is a recognized disease by the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow-up, and on safety precautions to be followed by personne, need to be requested from the relevant competent authorities.

- Pregnancy

  Birth defects attributed to high dosages of febantel have been reported in sheep and mice. 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. It is recommended that the product not be used in dogs during the first four weeks of pregnancy. Do not exceed the stated dosage when treating pregnant dogs.

- Reactions with other drugs and other types of interactions

  Do not use the product simultaneously with products containing piperazine, as the anthelmintic effects of pyrantel and piperazine may be contraindicated. Concurrent use with other cholinergic compounds (e.g., foxim) can lead to toxicity.

  If you are uncertain, and your dog is given other veterinary medicinal products, check with a veterinarian or pharmacist.

- Overdose

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

11. STORAGE INSTRUCTIONS

- Avoid poisoning! This medicine and any other medicine should be stored in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 25°C.

12. INSTRUCTIONS FOR DISPOSAL OF THE PRODUCT/RESIDUE AFTER COMPLETING USE

Immediately dispose of unused halved tablets.

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

Do not dispose of medicines via wastewater or the household waste. Ask your veterinarian how to dispose of medicines no longer required. This will help to protect the environment.

13. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Microcrystalline Cellulose, Lactose Monohydrate, Synthetic Pork Flavour, Sodium Laurilsulfate, Croscarmellose Sodium, Magnesium Stearate, Colloidal Anhydrous Silica.
  Each tablet contains 81.75 mg lactose monohydrate and 2.25 mg sodium.
- What the medicine looks like and the contents of the package
  Round, yellow pork-flavored tablets with a score line on one side.
  Marketed in packages of 24, 104 or 200 tablets.
  Not all package sizes may be marketed.

License holder: A.L.Medi-Market Ltd., 3 Hakatif St., Emek Hefer Industrial Park, 3877701.

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

Revised in October 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 157-34-34384-00