VETERINARY MEDICINE PACKAGE LEAFLET

This medicine is dispensed with a veterinarian's prescription only

For animal use only

1. NAME, FORM AND STRENGTH OF THE VETERINARY MEDICINE

Cazitel Plus Veterinary, Tablets

2. ACTIVE INGREDIENTS

Each tablet contains

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

The list of inactive ingredients is in section 13.

3. WHAT IS THE MEDICINE INTENDED FOR

In dogs: treatment of mixed infections by the following types of tapeworms (cestodes) and roundworms (nematodes):

Roundworms:

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

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

Whipworms: *Trichuris vulpis* (adults)

Tapeworms:

Tapeworms: *Echinococcus species* (*E. granulosus, E. multilocularis*), *Taenia species* (*T. hydatigena, T. pisiformis, T. taeniformis*), *Dipylidium caninum* (adult and immature forms).

Therapeutic group: Anthelmintic

ATC vet code: QP52AA51

4. CONTRAINDICATIONS

Do not use concomitantly with preparations containing piperazine.

Do not use in cases of hypersensitivity to the active ingredients or to any of the inactive ingredients.

5. SIDE EFFECTS

In very rare cases, side effects in the digestive system (diarrhea and vomiting) have been observed.

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: https://sideeffects.health.gov.il

6. TARGET SPECIES

Dogs

7. METHOD OF ADMINISTRATION AND DOSAGE

For oral administration only.

In order to ensure administration of the correct dosage, the body weight should be determined as accurately as possible.

The usual dosages are: 15 mg/kg body weight febantel, 5 mg/kg body weight pyrantel (equivalent to 14.4 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. These dosages are equivalent to one tablet per 10 kg body weight.

Dosage chart:

Body weight (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	One tablet per 10 kg

The tablet can be given directly to the dog or concealed in food. There is no need to starve the dog before or after administration. Underdosing could result in ineffective use and may favour resistance development.

The veterinarian should advise regarding the need and frequency of repeat administration.

8. HOW TO USE THE PREPARATION

The tablet can be divided into equal halves or quarters.

9. WITHDRAWAL PERIOD

Not applicable.

10. WARNINGS

- Special warnings regarding use in the target animal

  Fleas serve as intermediate hosts for the *Dipylidium caninum* type of tapeworm. Tapeworm infestation is certain to reoccur, unless control of pests such as fleas, mice, etc. is achieved.

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

  Parasite resistance to any type of anthelmintic may develop following frequent or repeated administration of anthelmintics of the same class.

  Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

  In the absence of risk of co-infection with roundworms or tapeworms, a narrow spectrum product should be used.

  The possibility that other animals in the same household can be a source of reinfection with roundworms and tapeworms should be considered, and these should be treated as necessary with an appropriate product.
- Special warnings regarding safety of use of the medicine in animals

  Unknown.
- Special warnings relating to the safety of the person administering the preparation

  If the preparation was accidentally swallowed, seek professional help immediately and show the leaflet or the label to the doctor.

  In order to maintain hygiene, wash hands thoroughly after directly administering the preparation to the dog, or to his food.
- Additional warnings

  Echinococcosis is hazardous for humans. As it is a notifiable disease to the World Organization for Animal Health (OIE), specific guidelines on the treatment, follow-up and human protection need to be obtained from the Israeli Health authorities.
- Pregnancy and lactation

  Febantel has teratogenic effects when administered at high dosages to sheep and rats. No studies have been performed in dogs in early stages of pregnancy. Use of the preparation 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 recommended dosage when treating pregnant dogs.
- Interactions with other medicines, and other forms of interactions

  Do not use concomitantly with piperazine compounds, due to risk of an antagonistic anthelmintic effect between piperazine and pyrantel.

  Concomitant use with cholinergic compounds may cause toxicity.
- Overdose

  The combination of pyrantel embonate, febantel and praziquantel is well tolerated by dogs. Safety tests have found that a single administration of 5 times or more of the recommended dosage occasionally caused vomiting.
- Incompatibility

  Unknown.

11. STORAGE INSTRUCTIONS

- Avoid poisoning! This medicine, and any other medicine, should be kept 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.
- Storage conditions - store the preparation below 25°C.

12. INSTRUCTIONS REGARDING DISPOSAL OF THE PREPARATION/REMNANTS OF THE PREPARATION AFTER USE

Dispose of any remaining veterinary medical preparation or waste obtained from using a veterinary medical preparation in the same manner as toxic waste; do not discard into a sewer.

13. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:

  Microcrystalline cellulose
  Lactose monohydrate
  Pork flavour Givaudan
  Sodium laurilsulfate
  Magnesium stearate
  Croscarmellose sodium
  Colloidal anhydrous silica
- What the medicine looks like and the contents of the package

  A round, flat, yellow tablet with cross breakline on one side and smooth on the other side. Tablet diameter: 13 mm.
- Package sizes

  The preparation can come in packages containing: 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 1,000 tablets.

  Not all package sizes may be marketed.
- **License holder:**

  Zoetis Israel Holding B.V., 5 Atir Yeda Street, Kfar Saba.
- **Manufacturer:**

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

Revised in February 2024 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 157-64-34312-00

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