CONSUMER PACKAGE INSERT FOR A VETERINARY PREPARATION

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved

The 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 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

4. CONTRAINDICATIONS

Do not use concomitantly with preparations containing piperazine.

Do not use in animals with a known sensitivity 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

6. TARGET SPECIES

Dogs

7. METHOD OF ADMINISTRATION AND DOSAGE

Single administration: 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 for every 10 kg body weight.

Dosage chart:

Body weight (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	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.

The veterinarian should consult 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 hosts for the *Dipylidium caninum* type of tapeworm. Worm infestation of this kind can reoccur unless control of pests such as fleas, mice, etc. is reached.
  Tapeworm infestation is uncommon 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.
- Special warnings regarding safety of use of the medicine in animals
  Unknown
- Special safety warnings relating to the safety of the person administering the preparation
  If the preparation was accidentally swallowed, seek professional help and show the leaflet to the doctor.
  In order to maintain hygiene, wash the hands thoroughly after directly administering the preparation to the dog, or to his food.
  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.
- Additional warnings
  Unknown
- Pregnancy and lactation
  Febantel has teratogenic effects when administered at high dosages to sheep and rats. No studies have been performed in bitches in early stages of pregnancy. The veterinarian should weigh the risk versus benefit before using this preparation during pregnancy. It is recommended not to use the preparation during the first 4 weeks of pregnancy.
  Do not exceed the recommended dosage when treating pregnant bitches.
- 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 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 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 - below 25°C.

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

Any unused veterinary medical preparation or any waste materials derived from use of a veterinary medical preparation should be disposed of as toxic waste; do not discard into the wastewater.

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 a crossed score line 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 1000 tablets
  Not all package sizes may be marketed
- License holder
  Zoetis Israel Holding B.V., 5 Atir Yeda Steet, Kfar Saba
- Manufacturer
  Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea Co. Galway, Ireland

This leaflet was checked and approved by the Ministry of Health in 12/2016.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

157-64-34312-00