APPROVED
by Rosselkhoznadzor
on 29 January 2019

7-8246

INSTRUCTION
for use of the veterinary drug
Prazitel® tablets

(Developer: **LLC “RESEARCH AND PRODUCTION COMPANY "SKIFF"**,
20, bldg 3, Nauchny proezd, Moscow, 117246)

Registration Certificate No.: 77-3-23.11-4406№PVR-3-3.5/01545

I. General Information

1. The veterinary drug’s trade name: Prazitel® tablets (Prazitel tabulettae).

Generic name: praziquantel, pyrantel.

2. Pharmaceutical form: oral tablets.

Prazitel® tablets are available in two dosages containing in one tablet the following active ingredients:

Prazitel® tablets for cats (320 mg): praziquantel - 20.0 mg and pyrantel pamoat – 200.0 mg;

Prazitel® tablets for kittens and puppies (100 mg): praziquantel - 5.0 mg and pyrantel pamoat – 50.0 mg.

Prazitel® tablets contain the following excipients: lactose, potato starch, calcium stearate, gelatin, crosscarmellose sodium.

3. The drug is a tablet of round, flat-cylindrical shape with a chamfer, a score line and a logo "ПР", light yellow with a greenish tint, speckles are allowed.

The shelf life of the drug is 3 years from the date of manufacture subject to storage conditions in sealed original packaging.

Do not use Prazitel® tablets after the expiration date.

4. Prazitel® tablets are packed in blisters or strips of 2 tablets in each. Each blister (strip) is packed in a cardboard box with package insert and labels for the pet passport.

5. Store Prazitel® tablets in the sealed original packaging, in a dark place, separate from food and feed, at a temperature of minus 10 to 25 °C.

6. Keep Prazitel® tablets out of the reach of children.

7. Any unused drug is disposed of in accordance with the law requirements.

8. Prescription status: over-the counter product.

II. Pharmacological Properties

9. Pharmacological class: anthelmintic agents in combinations.

10. The combination of praziquantel and pyrantel pamoate included in the drug provides a wide range of anthelmintic effects on roundworms and tapeworms found

in cats, kittens and puppies, including Toxocara spp., Toxascaris leonina, Uncinaria stenocephala, Ancylostoma spp., Echinococcus granulosus, Alveococcus multilocularis, Mesocestoides lineatus, Taenia spp., Dipylidium caninum, Diphyllobothrium latum.

Praziquantel is a compound of the pyrazinisoquinoline group, its mechanism of action is based on the induction of tegument decomposition, persistent depolarization of the helminth muscular cells, impaired energy metabolism, thus causing paralysis and death of cestodes and facilitating their removal from the gastrointestinal tract. The compound is rapidly absorbed in the gastrointestinal tract, achieving a maximum concentration in blood plasma after 1-3 hours, reversibly binds to blood serum proteins (70-80 %), is partially metabolized in the liver, re-excreted into the intestines, excreted mainly in urine (up to 80 %) within 24 hours.

Pyrantel pamoate is a compound of the pyrimidine group, its mechanism of action is based on blocking the transmission of nerve impulses in neuromuscular synapses by depolarizing the muscle cell membranes, thereby causing paralysis of the muscular system of nematodes; pyrantel is poorly absorbed, which ensures its prolonged effect on helminths in the intestine; it is excreted mainly in unchanged form in feces (93 %) within 24 to 48 hours.

Prazitel® tablets belong to moderately hazardous substances in terms of the degree of effects on the body (Hazard Class 3 according to GOST 12.1.007), it does not have immunotoxic, sensitizing, embryotoxic and teratogenic effects if used in recommended doses.

III. Treatment

11. Prazitel® tablets are prescribed preventively and medicinally for cats, kittens from the age of 3 weeks and puppies from the age of 2 weeks with nematodoses (toxocariasis, toxascaridosis, uncinariosis, ankylostomosis), cestodoses (echinococcosis, alveococcosis, mesocestoidosis, dog tapeworm, diphyllobothriasis) and combined nematode-cestodose invasions.

12. A contraindication to the use of Prazitel® tablets is an increased individual sensitivity of the pet to the components of the drug, including in past medical history, pronounced renal and hepatic disorders. Do not deworm animals that are emaciated, suffering from infectious diseases.

13. When using Prazitel® tablets, observe the general rules of personal hygiene and safety precautions provided for work with medicines. After work, wash your hands with warm water and soap. People with hypersensitivity to the drug components should avoid direct contact with Prazitel® tablets. Never use empty package of the drug for domestic purposes; it must be disposed of with household waste.

In case of allergic reactions or if accidentally swallowed the drug, immediately seek medical advice (show the instructions for use or label of the drug to the physician).

14. Do not use Prazitel® for females in the first half of pregnancy. Deworming of pregnant and lactating cats, if necessary, is carried out as prescribed by a veterinarian three weeks before the expected birth or 2-3 weeks after the birth.

15. Prazitel® tablets are used medically and preventively individually, once in

the morning feeding with a small amount of food (in a piece of sausage, meat, minced meat, porridge). In case of a severe invasion, it is recommended to repeat deworming in 10 days.

Dosage of Prazitel® tablets for cats for adult cats is 1 tablet per 4 kg of body weight of the pet; dosage of Prazitel® tablets for kittens and puppies for kittens and puppies is 1 tablet per 1 kg of body weight of the pet.

Preventive deworming in cats is carried out every 3 months and 10 days before vaccination. Preventive deworming in kittens is carried out every 3 months, starting from the age of 3 weeks. Preventive deworming of puppies is carried out at the age of 2 weeks, then at 4-6 weeks, at 6 months, depending on the vaccination schedule.

No preliminary fasting diet or the use of laxatives is required.

16. No side effects or complications following the use of the drug in accordance with these instructions are observed. With increased individual sensitivity to the components of the drug and the appearance of allergic reactions, the use of Prazitel® tablets is stopped and antihistamines and supportive care are prescribed for the animal.

17. In case of drug overdose, an animal may experience depression, food refusal, excessive salivation, disorders of the gastrointestinal tract. In these cases, enterosorbents and supportive care are prescribed for the animal.

18. Prazitel® suspension should not be used simultaneously with piperazine, levamisole and cholinesterase inhibiting agents, due to the possible mutual increase in toxicity.

19. There are no specific features of the action during the first use or withdrawal of Prazitel® tablets.

20. During deworming, the recommended instruction dates should be complied with. If a next deworming is skipped, the drug is administered in the same dosage with the same regimen.

21. Prazitel® tablets are not intended for productive animals.

Name and address of the production site of the veterinary drug manufacturer.	Innovative Enterprise Astrapharm, LLC; 20, bldg 3, Nauchny proezd, Moscow, 117246. tel/fax: (495) 785-83-50/70.
Name, address of the organization authorized by the holder or owner of the marketing authorization to accept consumer complaints.	Innovative Enterprise Astrapharm, LLC; 20, bldg 3, Nauchny proezd, Moscow, 117246. tel/fax: (495) 785-83-50/70.

Upon the approval of this prescribing information, the package insert for Prazitel® tablets approved by Rosselkhoznadzor on 27 June 2017 shall no longer be in force.