

**FEBTAL®
tablets**

PACKAGE LEAFLET

for veterinary use of the drug product FEBTAL® tablets

Approved by: N.A. Vlasov, the Deputy Head of the Federal Service for
Veterinary and Phytosanitary Surveillance

(Development organization: NVTs Agrovetzashchita Ltd., bld. 2, 4, Igarskii
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Marketing Authorisation No.: 77-3-7.17-4428 No. IIBP-2-1.9/00109

I. General

The name of the drug product for veterinary use:

Trade name: FEBTAL® tablets;

International nonproprietary name: fenbendazole.

Dosage form: tablets for oral administration.

1 tablet contains 150 mg of fenbendazole as an active ingredient as well potato starch, lactose, flavoring additive "taste of meat" and calcium stearate as excipients.

Appearance: interspersed round tablets from white or almost white to gray with a line on one side and a logo (cross in the center of the shield) on the other. The shelf life of the drug product in a sealed manufacturer's packaging is 3 years from the date of manufacture. It is forbidden to use the drug product after the expiration date.

The drug is produced in blisters containing 3 and 6 tablets packed in cardboard boxes along with a package leaflet Store FEBTAL® tablets in a sealed manufacturer's package protected from direct sunlight, separate from food and feed, at a temperature from 0°C to 25°C.

Keep out of reach of children.

Unused drug product should be disposed in accordance with legal requirements.

Available without prescription a veterinarian's prescription.

II. Pharmacological properties

FEBTAL® is an anthelmintic drug product.

Fenbendazole (5-phenyl-thio-2-benzimidazole carbamate), which is a compound of the benzimidazole group, has a wide spectrum of anti-nematode and cestode action, and is active against adult and larval forms of nematodes of the gastrointestinal tract and lungs, as well as cestodes and protozoa *Giardia* spp. parasitizing animals.

The mechanism of action of fenbendazole is the destruction of microtubules in the intestinal cells of helminths and disruption of energy processes, which leads to the death of parasites. The antiprotozoal effect on *Giardia* spp. is due to the ability of fenbendazole to form complex compounds with the parasite's DNA, which causes its degradation leading to the death of protozoa.

When administered orally, fenbendazole is readily absorbed in the intestine and distributed in the organs and tissues of the animal; it is excreted from the body in unchanged form and in the form of metabolites mainly with bile and partly with urine, in lactating animals also with milk.

In terms of the effect upon the animal body FEBTAL® tablets can be referred to moderately hazardous substances (hazard class 3 according to GOST 12.1.007-76) and well tolerated by animals in recommended doses.

III. Indications:

FEBTAL® tablets are prescribed to dogs and cats with a therapeutic and prophylactic purpose for giardiasis, nematodes (toxocariasis, toxascaridosis, ankylostomosis, ancylostomiasis), cestodosis (dipylidiosis, tapeworm infection, echinococcosis, alveococcosis) and the following nematode-cestode invasions:

– **nematodes:** *Toxocara canis*, *Toxocara cati*, *Toxascaris leonina*, *Ancylostoma caninum*, *Uncinaria stenocephala*;

– **cestodosis:** *Dipylidium caninum*, *Multiceps multiceps*, *Taenia hydatigena*, *Taenia ovis*, *Taenia pisiformis*, *Echinococcus granulosus*, *Alveococcus multilocularis*.

A contraindication to the use of FEBTAL® tablets is the individual hypersensitivity of the animal to the drug product ingredients. Do not use the drug product in emaciated, recovering animals and animals with infectious diseases.

Observe the general rules of personal hygiene and safety measures working with FEBTAL® tablets. After finishing work, wash your hands with warm water and soap. It is prohibited to use drug product empty containers for household purposes; they must be disposed with household waste.

In case of skin or eye contact, immediately rinse with plenty of water. People with hypersensitivity to the drug product ingredients should avoid direct contact with FEBTAL® tablets. In case of allergic reactions or accidental ingestion of the drug product, immediately see a doctor (show a drug package leaflet or a label).

If necessary, deworming of female animals during pregnancy and feeding of offspring is carried out under the supervision of a veterinarian 3 weeks before the expected birth and 2-3 weeks after birth.

Do not use the drug in puppies and kittens younger than 3 weeks of age. For treatment of helminthiasis in adult dogs and cats, FEBTAL® tablets are administered orally (inside) with a single dose of 1 tablet per 1.5 kg of animal weight; and once a day for three days in a row with a single dose of 1 tablet per 3 kg of animal weight for puppies and kittens older than three weeks.

FEBTAL® tablets are used for treatment of adult dogs and cats, puppies, and kittens with giardiasis at a dose of 1 tablet per 3 kg of animal weight once a day for 3 consecutive days. No prior fasting diet or laxatives are required before deworming.

As a rule, side effects and complications are not observed if FEBTAL® tablets are used in accordance with this package leaflet. In case of increased sensitivity to the ingredients of the drug product and allergic reactions, the use of FEBTAL® tablets should be discontinued and antihistamines and symptomatic therapy should be prescribed to the animal.

In case of an overdose, the animal may experience a depression, refusal to eat, excessive salivation, and gastrointestinal upset. There are no specific means of detoxification; general measures are used to exert the drug from the body.

FEBTAL® tablets should not be used concurrently with other anthelmintic drug products. There is no information about the incompatibility of the drug with drugs of other pharmacological groups, feed, and feed additives. The side effects of the drug product action during its first use and withdrawal were not observed.

Avoid skipping the next dose of the drug, as this can lead to a decrease in therapeutic efficiency. If the next dose is missed, the drug is used according to the schedule established by this package leaflet.

FEBTAL® tablets are not intended for use in productive animals.

/AVZ

animal health/

Name and address of the production site of the manufacturer of the drug product for veterinary use:

AVZ S-P LTD., 1, Tsentralnaia str., Sergiyev Posad, Moscow region, 141305 Russia.

Name and address of the organization authorized by the marketing authorization holder or owner of the drug product to accept claims from the consumers: AVZ S-P LTD., 1, Tsentralnaia str. Sergiyev Posad, Moscow region, 141305 Russia.

24-hour hotline: 8-800-700-19-93 (toll free in Russia).

See information on product conformity assessment at: www.vetmag.ru.