

ALBEN® C

I. General

The name of the drug product for veterinary use:

Trade name - ALBEN® C; international nonproprietary names of active ingredients - albendazole, praziquantel.

Dosage form: tablets for oral administration.

1 tablet of ALBEN® C contains 250 mg of albendazole and 25 mg of praziquantel as active ingredients, and lactose and potato starch as excipients.

Appearance: the drug is a cream to gray flat tablet with a line on one side and a logo (a cross in the center of the shield) on the other.

The shelf life of the drug product, subject to the storage conditions is 3 years from the date of manufacture. It is forbidden to use the drug after the expiration date.

The drug product is packaged in 2, 3 and 6 tablet blisters, which are individually packed in cardboard boxes along with package leaflet.

Store the drug product in a sealed manufacturer's package protected from direct sunlight, separate from food and feed, at a temperature from minus 5°C to 25°C.

Keep out of reach of children.

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

Available without a veterinarian's prescription.

II. Pharmacological properties

ALBEN® C belongs to the group of anthelmintic agents in combinations.

The combination of active substances in the drug product provides a wide spectrum of its anthelmintic action at all stages of development of roundworms and tapeworms parasitizing in dogs and cats, including *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*, *Trichuris vulvis*, *Echloslos*, *Echinococcus multilocularis*, *Dipyllobothrium latum*, *Dipylidium caninum*, *Multiceps multiceps*, *Taenia spp.*, as well as the simplest *Giardia spp.*

Albendazole is a benzimidazole carbamate derivative and is active against adults and nematode larvae of the gastrointestinal tract and lungs, as well as cestode imago.

PACKAGE LEAFLET

for veterinary use of the drug product ALBEN® C

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The mechanism of action is associated with selective suppression of betatubulin polymerization, which leads to the destruction of cytoplasmic microtubules of the intestinal tract cells of the helminth; changing the course of biochemical processes, albendazole inhibits the utilization of glucose and inhibits the synthesis of ATP, blocks the movement of secretory granules and other organelles in the muscle cells of helminths causing their death. The antiprotozoal effect on *Giardia spp.* is due to the ability of albendazole to form complex compounds with the parasite's DNA, which causes its degradation leading to the death of protozoa.

When administered orally, albendazole is poorly absorbed in the gastrointestinal tract, converted in the liver to form metabolites of albendazole sulfoxide and then albendazole sulfone. It is excreted from the body mainly in the form of metabolites, mainly with bile and partly with urine and also with milk in lactating females.

Praziquantel is a compound of the pyrazinisoquinoline group, which is active against sexually mature and immature cestodes; the mechanism of its action is based on inducing the breakdown of tegument and inhibition of fumarate reductase, persistent depolarization of muscle cells of the helminth, disruption of energy metabolism, which causes paralysis and death of cestodes and facilitates their excretion from the gastrointestinal tract. Praziquantel is rapidly absorbed in the gastrointestinal tract reaching its maximum concentration in the blood plasma after 1-3 hours it is distributed in the organs and tissues of the animal. Praziquantel binds to serum proteins of the blood (70-80%), is partially metabolized in the liver, re-excreted in the intestine. It is excreted from the body mainly in the urine (up to 80%) within 24 hours. In terms of the effect upon the animal body ALBEN® C can be referred to low hazardous substances (hazard class 4 according to GOST 12.1.007-76), and is well tolerated by dogs and cats of different breeds in recommended doses.

III. Indications:

ALBEN® C is prescribed to dogs and cats with therapeutic and prophylactic purposes in case of nematodes (toxocariasis, toxascaridosis, uncinariosis, ankylostomosis), cestodiasis (taeniasis, dipylidiosis, echinococcosis, dipyllobothriasis, mesocestoidiasis) and lambliosis.

A contraindication to use ALBEN® C is the increased sensitivity of the animal to the ingredients of the drug product.

Observe the general rules of personal hygiene and safety measures working with ALBEN® C drug product. 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 ALBEN® C. In case of allergic reactions or accidental ingestion of the drug product into the human body, you should immediately see a doctor (you should take a drug package leaflet or a label with you). It is prohibited to use empty package of the drug product for household purposes, they must be disposed with household waste.

It's prohibited the use ALBEN® C for pregnant and lactating females, as well as puppies under 3 weeks of age and kittens under 3 months of age.

ALBEN® C is administered to dogs and cats orally (inside).

In case of helminthiasis a single dose of 1 tablet per 5 kg of animal weight is used in the morning with a small amount of food. For dogs and cats weighing less than 2.5 kg, 1 tablet of the drug product is crushed, suspended in 10 ml of drinking water, vigorously shaken and immediately administered to the animal using a syringe without a needle, at the rate of 1 ml of suspension per 0.5 kg of animal weight.

In case of lambliosis and helminthiasis complicated by lambliosis ALBEN® C is applied at a dose of 1 tablet per 10 kg of animal weight once a day for 5 days. For dogs and cats weighing less than 2.5 kg, 1 tablet of the drug is crushed, suspended in 20 ml of drinking water, vigorously

shaken and immediately administered to the animal using a syringe without a needle, at the rate of 1 ml of suspension per 0.5 kg of animal weight.

Animals are deworming for therapeutic purposes according to indications, and on a quarterly basis with a therapeutic dose for prevention purposes.

A preliminary fasting diet and the use of laxatives for animals are not required before deworming.

As a rule side effects and complications are not observed if the ALBEN® C drug product is used in accordance with this package leaflet. In case of increased sensitivity to the ingredients of the drug product and allergic reactions, its use is discontinued and antihistamines and symptomatic therapy are 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 egest the drug from the body.

ALBEN® C should not be used concurrently with other anthelmintic drug products. There is no information about the incompatibility of ALBEN® C with drugs of other pharmacological groups, feed and feed additives.

The side effects of the drug product action during its first use or withdrawal were not observed.

Avoid skipping the next dose of the drug, as this can lead to a decrease in therapeutic efficiency. If one dose is missed, the use of the drug should be resumed in the same dose and according to the same dosage schedule.

ALBEN® C is not intended for use for 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**.