

AZINOX
for dogs and cats

PACKAGE LEAFLET

for veterinary use of the drug product Azinox for dogs and cats

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.:

in Russia 77-3-7.0-4314 No. ИБП-2-1.2/00898 dated 16.11.201

I. General

The name of the drug product for veterinary use:

Trade name: Azinox for dogs and cats.

International nonproprietary name: praziquantel

Dosage form: tablets for oral use.

1 tablet of the drug product contains 50 mg of praziquantel as an active ingredient and lactose and potato starch as excipients.

Appearance: a white flat tablet with a line and a logo.

The shelf life of the drug product is 3 years from the date of manufacture provided the storage conditions are observed. It is recommended to place the unused part of the tablet in a blister and store it under the stated conditions until the next deworming, but not more than 3 months after opening the package. It is prohibited to use the drug product after the expiration date.

The drug product is produced in polymer film and foil blisters containing 3 or 6 tablets individually packed in cardboard boxes. Each consumer package contains a 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 0°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

Azinox for dogs and cats is an anthelmintic drug product.

Praziquantel, an acylated derivative of pyrazine quinoline, which is part of the drug product, has a wide spectrum of cestodicidal action on all phases of development of tapeworms (cestodes) parasitizing in dogs and cats including *Echinococcus granulosus*, *Echinococcus multilocularis*, *Mesocostoides spp.*, *Taenia spp.*, *Dipylidium caninum* and *Diphyllbothrium latum*.

The mechanism of its action is based on inducing the degradation 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 promotes their excretion from the gastrointestinal tract.

Praziquantel is rapidly absorbed in the gastrointestinal tract reaching its maximum concentration in the blood plasma after 30-60 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 Azinox for dogs and cats can be referred to low hazardous substances (hazard class 4 according to GOST 12.1.007-76), it does not have embryotoxic, teratogenic and sensitizing effects in recommended doses.

The drug product is well tolerated by dogs and cats of different breeds and ages.

III. Indications:

Azinox for dogs and cats is prescribed for the treatment and prevention of diseases caused by tapeworms (dipylidiosis, diphyllbothriasis, mesocetoidiasis, tapeworm infection including echinococcosis).

A contraindication to the use of the drug product is a hypersensitivity of the animal to the drug product ingredients including in medical history, and severe renal and liver disorder. Animals with infectious diseases, weakened and recovering animals are not subject to deworming.

Observe the general rules of personal hygiene and safety measures working with Azinox for dogs and cats. People with hypersensitivity to the components of the preparation should avoid direct contact with Azinox for dogs and cats. In case of skin or eye contact immediately rinse with plenty of water. In case of allergic reactions or accidental ingestion of the drug product immediately see a doctor (take a drug package leaflet or a label).

If necessary, deworming of females 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. The drug product should not be used in puppies under 3 weeks of age.

Azinox for dogs and cats is used at a single dose by oral administration at a dose of 1 tablet per 10 kg of animal weight in the morning feeding with a small amount of feed.

The drug product is used in the form of an aqueous suspension for cats and dogs weighing less than 5 kg. ½ of a tablet is crushed, suspended in 5 ml of water, vigorously shaken, and immediately injected using a syringe without a needle at the rate of 1 ml of suspension per 1 kg of animal weight.

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

Dogs and cats are dewormed according to indications for therapeutic purposes and on a quarterly basis at a therapeutic dose for prevention purposes.

As a rule, side effects and complications are not observed if the drug product is used in accordance with this package leaflet. In case of increased sensitivity of animal to the drug product ingredients and allergic reactions the animal is prescribed antihistamines and symptomatic agents.

In case of significant overdose of the drug product, an animal may experience impaired motility of the gastrointestinal tract and depression.

Do not use Azinox for dogs and cats simultaneously with drugs containing piperazine and drugs that inhibit cholinesterase.

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

Violations of the recommended timing for deworming of animals should be avoided, as it is liable to cause a decrease in therapeutic effectiveness. If the next deworming treatment is missed the drug is used in the dose and according to the schedule established by this package leaflet. Azinox for dogs and cats 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**.