

**Ear Drops
BARS®**

PACKAGE LEAFLET

for use of ear drops BARS® for dogs and cats with otoacariasis

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

(Development organization: NVTs Agrovetzashchita Ltd., bld. 1, 1, Kolskaia St., Moscow, 129329 Russia).

I. General

Trade name: Ear Drops BARS®. International nonproprietary names of active ingredients: diazinon, prednisolone.

Dosage form: ear drops.

1 ml of Ear Drops BARS® contains 0.5 mg of diazinon and 0.3 mg of prednisolone as active ingredients, and also glycerin and isopropyl alcohol as excipients.

Appearance: a clear light green liquid.

The shelf life of a drug product is 2 years from the date of manufacture and 28 days after the first opening of the vial provided the storage conditions in a closed vial are observed.

It is prohibited to use the drug product after the expiration date.

Ear Drops BARS® are produced in 5 and 10-ml glass bottles sealed with rubber stoppers and aluminum rolled flip-offs; in 15, 20 and 30 ml polymeric dropper bottles sealed with polymeric caps; in 5 ml polymer dropper pipettes for single use. Glass vials and polymer dropper vials are packaged individually in cardboard boxes along with a package leaflet, and dropper pipettes are packaged in cardboard boxes containing 4 pieces along with 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

Ear Drops Bars® are combined drugs with a combination of antibacterial and fungicidal action.

Diazinon, which is part of the drug, is an organophosphorus compound of intestinal action, it has a pronounced acaricidal activity against larval and mature phases of development of ticks parasitizing on dogs and cats including the causative agent of otoacariasis of dogs and cats - Otodectes cynotis

Prednisolone is a synthetic glucocorticosteroid that has anti-inflammatory and anti-allergic effects, it stabilizes the permeability of cell membranes, prevents the production of inflammatory mediators, has antipruritic and anti-edematous effects.

In terms of the effect upon the animal body Ear Drops Bars® can be referred to moderately hazardous substances (hazard class 3 according to GOST 12.1.007), they do not have resorptive-toxic, local irritating and sensitizing effects in recommended doses but are Irritating to eyes.

III. Indications:

Ear drops Bars® are prescribed for dogs and cats for the treatment of otoacariasis (ear scabies).

A contraindication to use is the increased individual sensitivity of the animal to the ingredients of the drug product. It is forbidden to use the drug in animals with tympanic membrane perforation.

Ear auricles and auditory passages are cleaned from scabs and impurities with a tampon moistened with a small amount of the drug product, then 3-5 drops of the drug are instilled into the auditory canal of each ear (3-4 drops for cats and small dogs, 4 drops for medium dogs and 5 drops for large dogs).

The auricle is folded in half lengthwise and its base is lightly massaged for a complete treatment of the entire surface of ear auricle.

The treatment is carried out twice with a 5-7-day interval until the animal's clinical recovery, which is confirmed by microscopic examinations of scrapings. If necessary, the course of treatment is repeated.

The drug product must be injected into both ears, even if only one ear is affected by otoacariasis.

If the animal shakes its head, its head should be fixed for several minutes to prevent splashing of the drug product. In case of an overdose or ingestion, the animal may experience excessive salivation, muscle tremors, and vomiting. Symptomatic and desensitizing therapy is performed in this case.

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

It is forbidden to administer the drug to pregnant female animals. If necessary, the drug product can be used in animals during lactation under the supervision of a veterinarian. The drug product should not be used in puppies under 4 weeks of age.

Violations of the drug use regimen should be avoided, as it can lead to a treatment effectiveness decrease. If the following treatment is missed, it should be carried out as soon as possible in the same dose.

As a rule, side effects and complications are not observed if Ear Drops Bars® are used in accordance with this package leaflet.

In case of increased individual sensitivity and allergic reactions (itching, increased salivation, vomiting) to the drug product ingredients, the use of the drug product is stopped and desensitizing therapy is carried out.

Ear Drops Bars® should not be used simultaneously with other acaricidal drug products for animals. There is no information about the incompatibility of the drug with drugs of other pharmacological groups and feed additives.

The drug product is not intended for use in productive animals.

IV. Personal preventive measures

The requirements set to personal hygiene and labor safety and health regulations imposed on handling drug products must be complied with while handling Ear drops Bars®. It is prohibited to smoke, drink or eat while using the drug product. The requirements set to personal hygiene and labor safety and health regulations imposed on handling drug products must be complied with while handling. It is prohibited to use empty package where the drug product has been contained for household purposes – the packages must be disposed of with solid waste.

At incidental contact of the drug product with skin or eye mucosa rinse thoroughly with plenty of water. People with hypersensitivity to the ingredients of the drug product must avoid direct contacting with Ear Drops Bars®. %In the event of occurrence of allergic reactions or at incidental swallowing of the drug product consult the physician immediately (take away with you this package leaflet or the drug product label).

Marketing Authorisation No.: in Russia 77-3-7.0-3713 No. ПИБП -2-1.9/00110 dated 02.05.17

The package leaflet of Ear Drops Bars® approved by the Federal Service for Veterinary and Phytosanitary Surveillance on December 30, 2010 becomes invalid with the approval of this package leaflet.

/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**.