

**Guttae auriculares
BARS® FORTE**

PACKAGE LEAFLET

for use of Guttae auriculares Bars® forte for the treatment of otitis media in 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. 1, 1, Kolskaia St., Moscow, 129329 Russia)

I. General

Trade name: Guttae auriculares Bars® forte.
International nonproprietary name: miconazole, enrofloxacin.

Dosage form: ear drops.

1 ml of guttae auriculares Bars® forte contains 20 mg of miconazole nitrate and 3 mg of enrofloxacin as active ingredients, as well as an isopropyl alcohol as excipients.

Appearance: a liquid from dark yellow to brown in color, which may have opalescence.

The shelf life of the drug product is 2 years from the date of manufacture and 28 days after the first opening of the package provided the storage conditions are observed. It is prohibited use Guttae auriculares Bars® forte after the expiration date.

Guttae auriculares Bars® forte 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 vials, 20, 30 and 50 ml glass dropper vials with a dropper plug sealed with a plastic cap. Dropper vials and glass vials are individually packed in cardboard boxes along with a package leaflet. Store Guttae auriculares Bars® forte 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

Guttae auriculares Bars® forte are combined drug products with a combination of antibacterial and fungicidal action.

Combinations of active ingredients with different mechanisms of action provide a wide range of antibacterial, and antifungal effects.

Miconazole nitrate has fungicidal activity against *Candida* spp., *Aspergillus* spp., Dimorphous fungi, *Cryptococcus neoformans*, *Pityrosporum* spp., *Torulopsis glabrata* and bacteriostatic activity against some gram-positive bacteria secreted by otitis media in dogs and cats. The mechanism of action of miconazole is due to the ability to inhibit the biosynthesis of ergosterol of the membrane and plasma membranes of fungi, and to change the lipid composition and permeability of the microorganism cell wall.

Enrofloxacin is a compound of the fluoroquinolone group, which has a broad spectrum of antibacterial and anti-mycoplasma activity. It suppresses the

growth and development of gram-positive and gram-negative bacteria including *Staphylococcus* spp., *Streptococcus* spp., *Proteus* spp., and *Mycoplasma* spp.

The mechanism of action of enrofloxacin is to inhibit the activity of the enzyme gyrase, which affects the replication of the DNA helix in the nucleus of the bacterial cell, which leads to disruption of protein synthesis, rapid death of the bacterial cell and suppression of the local tissue .

In terms of the effect upon the animal body Guttae auriculares Bars® forte can be referred to low hazardous substances (hazard class 4 according to GOST 12.1.007-76), they do not have resorptive-toxic, irritating skin effects in recommended doses but are irritating to eyes.

III. Indications:

Guttae auriculares Bars® forte are prescribed to dogs and cats for the treatment of acute and chronic otitis media of bacterial and fungal etiology.

Contraindication to the use of Guttae auriculares Bars® forte is the increased individual sensitivity of the animal to the drug product ingredients.

It is forbidden to use the drug product for the treatment of otitis media with perforation of the tympanic membrane.

Guttae auriculares Bars® forte are applied to ears. 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 and the auditory passage and deeper penetration of drops.

The drug product is used 2 times a day for 5-7 days. If necessary, the course of treatment is repeated after a week's interval.

If the animal shakes its head it's should be fixed for several minutes to prevent splashing of the drug product.

Symptoms of a drug overdose have not been identified.

The side effects of the drug product action during its first use and withdrawal were not observed. Guttae auriculares Bars® forte are used for pregnant or lactating females, puppies and kittens with caution as directed and under the supervision of a veterinarian.

Avoid skipping the next dose of the drug as it can

lead to a therapeutic effectiveness decrease. If one dose is missed, the use of the drug should be resumed in the same dose and according to the same dosage schedule.

As a rule, side effects and complications are not observed if Guttæ auriculares Bars® forte is 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 Guttæ auriculares Bars® forte should be discontinued and, if necessary, antihistamines and symptomatic therapy should be prescribed to the animal.

Guttæ auriculares Bars® forte should not be used concurrently with other drugs for auricular use.

Guttæ auriculares Bars® forte is not intended for use by 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 Guttæ auriculares Bars® forte.

It is prohibited to smoke, drink or eat while using the drug product. After handling the drug product wash your hands with soap and lukewarm water. People with hypersensitivity to the ingredients of the drug product must avoid direct contacting with Guttæ auriculares Bars® forte.

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. 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 77-3-4.17-3681 No.IIBP-3-6.8/02233 dated 13.04.17

/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**.