

EYE DROPS BARS®

PACKAGE LEAFLET

for veterinary use of the drug product Eye drops BARS®

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

(Development organization: NVTs Agrovetzashchita Ltd., bld. 2, 4, Igarskii passage, Moscow, 129329 Russia)

Marketing Authorisation No.: 77-3-4.17-3680 No. IIBP-2-1.5/01454

I. General

The name of the drug product for veterinary use:

Trade name: Eye drops BARS®

International nonproprietary names:
chloramphenicol, nitrofur

Dosage form: eye drops.

1 ml of Eye drops BARS® contains 2.5 mg of chloramphenicol (chloramphenicol) and 0.2 mg of furacilin (nitrofur) as active ingredients, and benzalkonium chloride and water for injection as excipients.

Appearance: a clear greenish-yellow liquid.

The shelf life of the drug product is 2 years from the date of manufacture and 30 days after the first opening of the vial provided the storage conditions in a closed vial are observed. It is forbidden to use the drug product after the expiration date.

The drug product is produced in 10 ml polymer dropper bottles sealed with screw-on polymer tamper-evident caps and individually packed in cardboard boxes 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 5°C to 25°C. After the first opening, the vial is stored for 30 days in a refrigerator.

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

Eye drops BARS® is a complex ophthalmic antibacterial drug of a wide spectrum of action. Levomycetin, which is part of the drug, is active against most gram-positive and gram-negative microorganisms and some large viruses; it is active against strains tolerant to penicillin, streptomycin, sulfonamides. It is weakly active against acid-fast bacteria, pseudomonas aeruginosa, clostridia and protozoa.

The mechanism of action of chloramphenicol is in the inhibition of peptidyl transferase, which leads to disruption of protein synthesis in the bacterial cell. Furacilin has bacteriostatic and bactericidal action against a wide range of pathogenic gram-positive and gram-negative microorganisms; it is active against microorganisms resistant to other antimicrobial agents (not from the group of nitrofur derivatives). It has an antimicrobial action.

The mechanism of action of furacilin consists in the formation of highly reactive amino derivatives that

cause conformational changes in proteins (including ribosomal ones) and other macromolecules leading to the death of microorganisms.

When instilled into the conjunctival cavity, the drug product penetrates well into the tissues of the eye providing a stable therapeutic level of active substances for 6-8 hours.

In terms of the effect upon the animal body Eye drops BARS® can be referred to low hazardous substances (hazard class 4 according to GOST 12.1.007).

III. Indications:

Eye drops BARS® are prescribed for dogs, cats, and rabbits of fancy breeds with the following ophthalmological indications:

- for the treatment of acute and chronic conjunctivitis, keratitis, keratoconjunctivitis and blepharitis, in the complex therapy of viral eye diseases, as well as for cleansing and disinfecting wounds of the conjunctiva and eyelids;
- in order to reduce the risk of ocular infections after trauma and foreign bodies, as well as for ocular surgery during the preoperative and postoperative periods.

A contraindication to use is the increased individual sensitivity of the animal to the ingredients of the drug product.

Observe the general rules of personal hygiene and safety measures provided for when working with Eye drops BARS®. In case of skin or eye contact immediately rinse with plenty of water. People with hypersensitivity to the drug ingredients should avoid direct contact with Eye drops BARS®. In case of allergic reactions or accidental ingestion of the drug product immediately see a doctor (show a drug package leaflet or a label).

It is prohibited to use drug product empty containers for household purposes they must be disposed with household waste.

Usage of the drug product for animals during pregnancy and lactation, as well as in offspring is determined by a veterinarian based on an assessment of the correspondence of the benefits to the possible risk of its use.

Eye drops BARS® are used for dogs, cats, and rabbits of fancy breeds. Hygienic treatment of eyes with a sterile gauze pad moistened with the drug product is preliminarily carried out before using the drug product to cleanse and disinfect wounds of the conjunctiva and eyelids, remove mucous, purulent, mucopurulent exudate. Then the drug product is instilled into the conjunctival cavity at a rate of 1-2 drops 3-4 times a day for 7-14 days. Hygienic treatment of the eyes is carried out once a day with a sterile gauze nap moistened with the drug product.

In order to reduce the risk of eye infections with eye injuries, Eye drops BARS® are instilled into the conjunctival cavity at a dose of 3-4 drops 2-3 times a day for 1-2 days.

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 to the ingredients of the drug product and allergic reactions, its use is discontinued, antihistamines and symptomatic therapy are prescribed to the animal.

Symptoms of drug overdose in animals have not been identified. There is no information about the incompatibility of Eye drops BARS® with drug products of other pharmacological groups and feed additives.

The side effects of the drug product action during its first use and withdrawal were not observed. Violations of the dosage schedule should be avoided, as it can lead to an effectiveness decrease. If one dose is missed the use of the drug product should be resumed at the same dose and according to the same dosage schedule.

/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**.