

**Eye drops
IRIS**

PACKAGE LEAFLET

for veterinary use of the drug product Eye drops IRIS

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)

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I. General

The name of the drug product for veterinary use:

Trade name: Eye drops IRIS

International nonproprietary name: gentamicin.

Dosage form: eye drops.

The drug product contains 4 mg/ml of gentamicin sulfate as an active ingredient, as well as tread grade sodium pyrosulfite, versene, medium molecular weight medical polyvinylpyrrolidone and water for injection as excipients.

Appearance: a clear, light yellow liquid.

The shelf life of a drug product is 3 years from the date of manufacture and 10 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.

Eye drops IRIS are packed in 10 ml polymeric dropper bottles sealed with screw-on polymeric tamper-evident caps. Dropper bottles are packed in individual cardboard boxes. Each consumer package is accompanied by a package leaflet. Store the medicinal product in the manufacturer's closed packaging protected from direct sunlight and separately from food and feed, at a temperature of 5°C to 25°C.

Keep out of reach of children.

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

Available without prescription a veterinarian's prescription.

II. Pharmacological properties

Eye drops IRIS belong to the pharmacotherapeutic group: ophthalmic agents.

Sulfate, which is part of the preparation gentamicin, has a bactericidal effect on most gram-positive and gram-negative bacteria including *Pseudomonas aeruginosa*. It does not affect anaerobic bacteria, fungi, viruses, and protozoa. The mechanism of action of gentamicin is based on the inhibition of peptide bonds during the synthesis of proteins in the ribosomes of a bacterial cell.

Eye drops IRIS easily penetrate into the intraocular (internal) medium of the eye and reduce the risk of microbial infection in case of eyeball injuries due to the prolonged action of gentamicin.

In terms of the effect upon the animal body Eye drops IRIS can be referred to low hazardous substances (hazard class 4 according to GOST 12.1.07-76), and do not have local irritating and resorptive-toxic effects in recommended doses.

III. Indications:

Eye drops IRIS are used for dogs and cats with therapeutic and preventive purposes for acute and chronic conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers and erosions, meibomitis, blepharitis and iridocyclitis (uveitis), as well as for reducing the risk of foreign body and other irritating agents.

A contraindication to the use of Eye drops IRIS is the individual hypersensitivity of the animal to the drug product ingredients

Observe the general rules of personal hygiene and safety measures working with Eye drops IRIS. 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 IRIS. 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 empty package of the drug product for household purposes, they must be disposed with household waste.

Eye drops IRIS are approved for use by animals during pregnancy and lactation.

Eye drops IRIS with therapeutic and therapeutic and prevention purposes are instilled into the conjunctival cavity 4 times a day for 7-10 days at the doses indicated in the table:

Species	Number of drops for one treatment
Dogs, up to 10 kg	1
Dogs from 10 kg and more	2
Cats (any weight)	1

The drug product is administered at a dose of 1 drop 4 times a day for 3 days in order to reduce the risk of eye infections when a foreign body and other irritating agents get into the eye.

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 and 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 the drug product with drugs of other pharmacological groups and feed additives.

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

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

Eye drops IRIS are not intended for use in 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.