

KirOfthal Tobra

REGISTRATION NUMBER Q-0790-134

FORMULATION:

Each mL contains:

Tobramycin 3 mg
 Chondroitin sulfate 100 mg
 Vehicle q.s. 1 mL

DOSAGE SIZE AND FORM: 5 mL Dropper bottle

VETERINARY USE

OPHTHALMIC SOLUTION

Tobramycin / Chondroitin sulfate

Broad-spectrum antibiotic



DESCRIPTION:

It is a solution in ophthalmic drops with antibiotic action. In addition, it helps the regeneration and reorganization of the epithelium.

INDICATIONS:

It is indicated in the treatment of external infections of the eye and its adjacent areas such as blepharitis, conjunctivitis, keratoconjunctivitis, corneal infection by *Staphylococcus spp*, as well as adjuvant in the treatment of severe intraocular infections, caused by susceptible bacteria. As well as for pre-surgical and post-surgical prophylaxis of the eye in dogs and cats.

PHARMACOLOGY:

Tobramycin is an aminoglycoside antibiotic obtained from the cultures of *Streptomyces tenebrarius*. Chemically considered as a natural deoxikanamycin. The drug crosses the bacterial membrane by active and ribosomal transport. It acts by interfering with the initiation complex between messenger RNA and 30s ribosomal subunit, thus inhibiting protein synthesis. As a result, RNA is interpreted incorrectly, thus producing non-functional proteins, making it bactericidal.

Tobramycin is active against many gram-negative aerobic bacteria and some gram-positive bacteria, it is active against most strains of *Acinetobacter calcoaceticus*, *Bordetella spp*, *Enterobacter aerogenes*, *Escherichia coli*, *Haemophilus influenzae*, *H. aegyptius*, *Moxarella spp.*, some strains of *Neisseria sp.*, *Klebsiella pneumoniae*, *Morganella morganii*, *Proteus sp.*, *Mirabilis sp.*, and most strains of *Proteus vulgaris sp.*, *Pseudomonas aeruginosa*, *Serratia sp.*, *Staphylococcus aureus*, *S. epidermidis* including penicillin-resistant strains, *Streptococci* including beta-hemolytic species of group A and some non-hemolytic species and some strains of *Streptococcus pneumoniae*. It has controlled virtually all conjunctivitis-producing species in dogs. It is remarkably active against *Actynobacillus pleuropneumoniae*.

PHARMACOKINETICS:

The ocular pharmacokinetics of tobramycin, shows that a significant concentration of tobramycin with therapeutically effective levels against *Pseudomonas aeruginosa* and *S. aureus*, were reached at 15 minutes of sampling. A peak concentration of 3.24 mg/L was recorded at two hours and therapeutic levels (to cover most susceptible microorganisms) were recovered in the last estimated samples at 6 hours.



In studies, tobramycin was found to have a terminal half-life of 154 minutes in tears, and the average residence time on the tear was 106 minutes without chondroitin sulfate, and the average time the drug remained above the minimum inhibitory concentration (MIC) for five bacterial species was 251 minutes.

The **chondroitin sulfate** is a glycosaminoglycan associated with proteins (proteoglycans) is of high molecular weight and may be constituted by more than 100 sugars. It acts as a natural polymer found in most tissues of vertebrates and invertebrates and is present mainly in those that have a large extracellular matrix as part of the connective tissue of the body (skin, cartilage, blood vessels, ligaments and tendons). It has the characteristic of forming solutions of high viscosity and low opalescence, so it is used as a viscosifying agent in formulations. It also inhibits the proteolytic enzymes contained in tears, these enzymes increase during inflammation and some are produced by bacteria, such as *Pseudomona aeruginosa*, therefore, chondroitin sulfate promote cell growth and ulcer healing, and promotes the production of fibronectin. It acts as a moisturizing and regenerating agent of the corneal epithelium due to its capacity to fix and retain water. Chondroitin sulfate has no intraocular penetration capacity; however, it increases the residence time of the precorneal tear film.

SPECIES: Canines and felines

DOSE:

Apply 1 drop in the affected eye every 8 - 12 hours during the first 2 days and then 1 drop every 24 hours for 5 days or at the Veterinary Doctor's discretion.

ROUTE OF ADMINISTRATION:

Ophthalmic only

WARNINGS AND/OR RESTRICTIONS:

Discontinue use in case of sensitivity to the formulation. Keep in a dry, cool place, at a range of 15 to 30°C and protected against direct sunlight. Keep out of reach of children, pets and the disabled persons. Product for exclusive use in Veterinary Medicine.

KirOftal Tobra® is contraindicated in animal patients with hypersensitivity to any of the components of the formulation. Cross-hypersensitivity among aminoglycosides has been demonstrated, so the possibility that animal patients hypersensitive to other topical or systemic aminoglycosides may be hypersensitive to tobramycin should be considered.

CONSULT A VETERINARY DOCTOR
AVAILABLE BY PRESCRIPTION ONLY