

Gentob

Tobramycin

Sterile Eye Drops & Ointment

Presentation

Gentob Drops: Each ml sterile eye drops contains Tobramycin USP 3 mg.

Preservative: Benzalkonium Chloride 0.01%

Vehicle: Cremophor EL

Gentob Ointment: Each gram sterile eye ointment contains Tobramycin USP 3 mg.

Pharmacological Action

Like other aminoglycosides, the bactericidal activity of Tobramycin is taken up into sensitive bacterial cells by an active transport process. Within the cell Tobramycin bind to the 30s and to some extent to the 50s subunits of the bacterial ribosome, inhibiting protein synthesis and generating errors in the transcription of the genetic code.

Indications

Tobramycin eye drops is indicated for the treatment of external infections of the eye and its appendages such as bacterial conjunctivitis, keratitis, corneal ulcer caused by susceptible bacteria.

Dosage and Application

Gentob Drops: In mild to moderate infection, instill 1 drop 4/6 times daily into the conjunctival sac(s). In severe cases of infection, instill 1 drop hourly until improvement is obtained, then reduce the dose gradually. Duration of treatment is 5-15 days. Clinical studies have shown Tobramycin ophthalmic preparation to be safe and effective for use in children.

Gentob Ointment: In mild to moderate disease it should be applied thinly and evenly into the conjunctival sac of the affected eyes 2 to 3 times per day. For severe cases it should be applied thinly and evenly into the conjunctival sac of the affected eyes 3 to 4 times per day. Following improvement, treatment should be reduced prior to discontinuation.

Contraindications

In patient with known hypersensitivity to any component of the product. Partial cross-allergenicity to other aminoglycosides has been established.

Side Effects

The most frequent adverse reactions to Tobramycin are localized ocular toxicity and hypersensitivity, including lid itching and swelling and conjunctival erythema. These reactions occur in less than 3% of patients treated.

Precautions

As with other anti-infective, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy.

Drug Interactions

Specific drug interaction studies on Tobramycin ophthalmic preparation have not been established.

Use in Pregnancy and Lactation

There are no adequate data with respect to the ocular or systemic use of Tobramycin in pregnant women. Therefore, ophthalmic Tobramycin should be used during pregnancy only when potential benefits exceed the risks.

Aminoglycosides after systemic administration pass into the milk in low quantity. Breast-feeding is possible with ophthalmic Tobramycin considering the negligible amount of this substance possibly absorbed by the neonate.

Overdose

Not known and not likely in ophthalmic preparation.

Storage Conditions

Store in a cool and dry place away from light. Keep out of reach of children. Do not touch the dropper tip or tip of the tube since this may contaminate the medicine. After one month of the opening do not use the medicine of dropper or tube.

Commercial Pack

Gentob Drops: Each plastic dropper bottle containing 5 ml sterile eye drops.

Gentob Ointment: Each tube containing 3 gm sterile eye ointment.

Manufactured by :

 **GENERAL**
Pharmaceuticals Ltd.

Unit-2, Kaliakair, Gazipur, Bangladesh

Revision No.: 01
22060023