Ocutob™

Eye Drops

Composition:

Each ml of Ocutob eye drops contains:

Tobramycin	0.3% w/v
Sterile aqueous vehicle	q.s

Pharmacokinetics:

Tear film concentrations were studied in sixteen (16) healthy male and female subjects who were administered one drop of tobramycin solution in each eye daily for nine (9) consecutive days. It showed a significantly greater area under the tobramycin tear fluid concentration versus time curve (AUCI), a significantly greater area within the tobramycin tear fluid concentration versus time curve exceeding the minimal inhibitory concentration90 (AUC over MIC90), and a greater duration of time over which the tobramycin tear fluid concentrations remained above MIC90.

Mechanism of Action:

Ocutob contain bactericidal aminoglycoside antibiotic Tobramycin. Tobramycin produces its bactericidal action by binding with 30S subunit of the ribosome and inducing misreading of mRNA codons. Ocutob has a long post-antibiotic effect, which ensures the persistence of antimicrobial activity even when concentrations have fallen below the minimum inhibitory concentration. The antibacterial spectrum of Ocutob includes *Staphylococcus aureus*, *Staphylococcus epidermidis* (coagulase-positive and coagulase negative), *Streptococci* including Group A-beta-hemolytic species and Streptococcus pneumoniae, *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Proteus mirabilis*, *Morganella morganii*, *Proteus vulgaris*, *Haemophilus influenzae* and *H. aegyptius*. Ocutob is 2-4 times more active against *Pseudomonas* and *Proteus*, including those resistant to Gentamicin.

Indication:

- In ocular infection

Contraindication:

The use of Ocutob is contraindicated in patients with known hypersensitivity to any of the ingredients of the formulation.

Adverse effects:

The most frequent adverse reactions to ocular Tobramycin are hypersensitivity and localized toxicity including lid itching, swelling and conjunctival erythema. If topical ocular Tobramycin is administered concomitantly with systemic aminoglycoside antibiotics, care should be taken to monitor the total serum concentration.

Warnings and Precautions:

As with other antibiotic preparations, prolonged use with Ocutob may result in overgrowth of non-susceptible organisms, including fungi. If super infection occurs, appropriate therapy should be initiated.
Sensitivity to topically applied aminoglycosides may occur in some patients. If a sensitivity reaction to Ocutob occurs, discontinue use.
Use of contact lenses should be discouraged in patients using Ocutob.
Safety and effectiveness in pediatric patients below the age of 2 years have not been established.

Use in special population:

1. **Pediatric:** Safety and effectiveness in pediatric patients below the age of two months has not been established.
2. **Geriatric:** No overall clinical differences in safety or effectiveness have been observed between elderly and younger patients.
3. **Liver impairment:** No data found.
4. **Renal failure:** No data found.
5. **Pregnancy and lactation:** Category B: Reproduction studies in three types of animals at doses up to thirty-three times the normal human systemic dose have revealed no evidence of impaired fertility or harm to the fetus due to tobramycin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

   Nursing Mothers: Because of the potential for adverse reactions in nursing infants from Ocutob, a decision should be made whether to discontinue nursing the infant or discontinue the drug, taking into account the importance of the drug to the mother.

Dosage:

As directed by physician.

Presentation:

5ml in plastic bottle.

Storage and handling:

Store at 2°C- 25°C (36°F - 77°F).