Ocutob™

Eye Drops

1. Generic Names

Tobramycin

2. Qualitative and Quantitative Composition

Each ml of Ocutob eye drops contains:

Tobramycin	0.3% w/v

3. Dosage form and strength

Topical ophthalmic solution containing Tobramycin 0.3%(0.3mg/100ml).

4. Clinical particulars

4.1 Therapeutic indication

Ocutob is indicated in ocular infection.

4.2 Posology and method of administration

As directed by physician.

4.3 Contraindication

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

4.4 Special warnings and precautions for use

- 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.

4.5 Drug interactions

Tobramycin has no known severe interactions with other drugs.

4.6 Use in special population

- Paediatric: Safety and effectiveness in paediatric patients below the age of 2 years have not been established.
- Geriatric: No overall clinical differences in safety or effectiveness have been observed between elderly and younger patients.
- Liver impairment: No data found.
- Renal failure: No data found.
- 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 foetus 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.

4.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Ocutob eye drop is known.

4.8 Undesirable 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.

4.9 Overdose

There is limited experience of overdose with Ocutob eye drop. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 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.

5.2 Pharmacodynamic properties

Tobramycin, an aminoglycoside antibiotic obtained from cultures of Streptomyces tenebrarius, is used in combination with other antibiotics to treat urinary tract infections, gynecologic infections, peritonitis, endocarditis, pneumonia, bacteraemia and sepsis, respiratory infections including those associated with cystic fibrosis, osteomyelitis, and diabetic foot and other soft-tissue infections. It acts primarily by disrupting protein synthesis, leading to altered cell membrane permeability, progressive disruption of the cell envelope, and eventual cell death. Tobramycin has in vitro activity against a wide range of gram-negative organisms including Pseudomonas aeruginosa.

5.3 Pharmacokinetic properties

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.

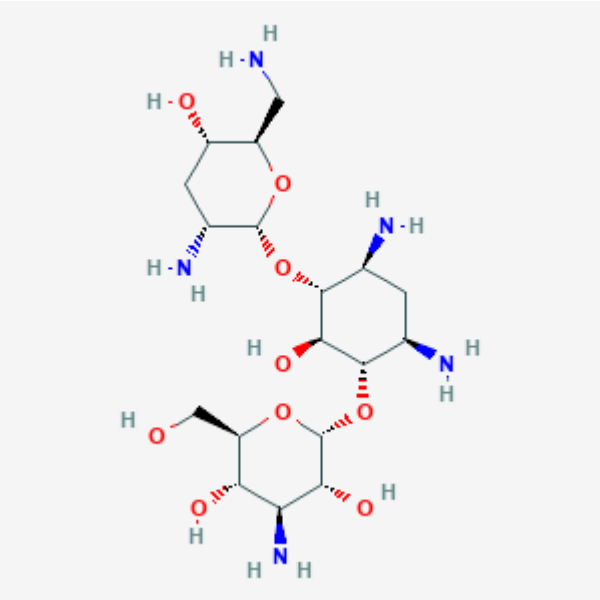
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Tobramycin is an aminoglycoside antibiotic derived from Streptomyces tenebrarius with bacteriostatic activity. The chemical name is (2*S*,3*R*,4*S*,5*S*,6*R*)-4-amino-2-[(1*S*,2*S*,3*R*,4*S*,6*R*)-4,6-diamino-3-[(2*R*,3*R*,5*S*,6*R*)-3-amino-6-(aminomethyl)-5-hydroxyoxan-2-yl]oxy-2-hydroxycyclohexyl]oxy-6-(hydroxymethyl)oxane-3,5-diol. Its empirical formula and molecular weight is $C_{18}H_{37}N_5O_9$ and 467.5 g/mol.



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24 months.

8.3 Packaging Information

Ocutob eye drop is available in 5ml in plastic bottle.

8.4 Storage and handling instructions

Store in cool and dry place.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by CENTAUR PHARMACEUTICALS PVT. LTD. and DCI Pharmaceuticals

11. Details of permission or license number with date

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