SUMMARY OF PRODUCT CHARACTERISTICS

1 Name of the Medicinal Product

Product Name: Tobramycin & Dexamethasone Ophthalmic Solution (OCUTOB-D STERILE EYE DROPS)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains,

Tobramycin sulphate USP equi.to Tobramycin. % w/v

Dexamethasone sodium phosphate BP..... % w/v

Benmzalkonium chloride solution BP.....% w/v

(as preservative)

Aqueous base..... q.s.

3. PHARMACEUTICAL FORM

Eye Drops

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

OCUTOB - D is indicated for the treatment of inflammatory conditions of,

- The palpebral and bulbar conjunctiva
- Cornea and anterior segment of the globe
- Chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or after foreign body removal
- Squamous blepharitis
- Prophylactically from 2nd or 3rd day of surgery

4.2 Posology and method of administration

The usual recommended dose of OCUTOB - D is 1-2 drops every 4-6

hours. During the initial 24-48 hours, the dosage may be increased to 1-2 drops every 2 hours. Frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.

4.3 Contraindications

The use of OCUTOB - D is contraindicated in patients with knownhypersensitivityto Tobramycin or Dexamethasone or any of the ingredients of the formulation.

4.4 Special warnings and precautions for use

OCUTOB - D is for ocular/otological use only and not for injection or oral use.

As with other antibiotic preparations, prolonged use with OCUTOB – D may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated Sensitivity to topically applied aminoglycosides may occur in some patients. If a sensitivity reaction to OCUTOB - D, discontinue use.
Use of contact lenses should be discouraged in patients using OCUTOB - D.

Safety and effectiveness in pediatric patients below the age of 2 years have not been established.

4.5 Interaction with other medicinal products and other forms of interaction

Specific drug interaction studies have not been conducted with ophthalmic Tobramycin. However, the systemic administration can promote kidney damage or hearing loss if taken with other Nephrotoxic and Ototoxic drugs. Some Nephrotoxic / Ototoxic drugs include: amikacin, amphotericin B, cidofovir, cisplatin, polymyxin B, cephalosporins such as cephaloridine, nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, among others.

4.6 Pregnancy and lactation

There are no adequate and well-controlled studies in pregnant women. OCUTOB - D should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Because many drugs are excreted in human milk, caution should be exercised when OCUTOB - D is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

There are no known effects of OCUTOB - D drops on the ability to drive & use machines. It is unlikely to have an effect.

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 concomitantly with systemic aminoglycoside antibiotics, care should be taken to monitor the total serum concentration.
The reactions due to the steroid component are elevation of intra-ocular pressure and infrequent optic nerve damage, posteriorsubcapsular cataract formation and delayed wound healing.

Reporting of suspected adverse reactions:
Healthcare professionals are requested to report any suspected adverse reactions via Pharmacy and the Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

A topical overdosage of OCUTOB - D Solution may be flushed from the eye(s) with warm tap water.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

OCUTOB – D contain bactericidal aminoglycoside antibiotic Tobramycin and Dexamethasone. Tobramycin produces its bactericidal action by binding with 30S subunit of the ribosome and inducing misreading of mRNA codons. OCUTOB - D 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 Tobramycin includes Staphylococcus aureus, Staphylococcus epidermidis (coagulase-positive and coagulasenegative), Streptococci including Group A-beta- hemolytic species and Streptococcus pneumoniae, Pseudomonas aeruginosa, Escherichia coli, Klebsiellapneumoniae, Enterobacteraerogenes, Proteus mirabilis, Morganellamorganii, Proteus vulgaris, Haemophilusinfluenzae and H. aegyptius. Dexamethasoneis a potent corticosteroid that suppresses the inflammatory response to a variety of agents.

5.2 Pharmacokinetic properties

Tobramycin, peak plasma concentrations are achieved within 30 to 90 minutes and concentrations of about 4 micrograms/mL have been reported following doses of 1 mg/kg. Usual doses by slow intravenous injection may result in plasma concentrations which briefly exceed 12 micrograms/mL. A plasma half-life of 2 to 3 hours has been reported.

Dexamethasone biological half-life in plasma is about 190 minutes. Binding of dexamethasone to plasma proteins is about 77%, which is less than for most other corticosteroids. Up to 65% of a dose is excreted in urine within 24 hours. Clearance in premature neonates is reported to be proportional to gestational age, with a reduced elimination rate in the most premature. It readily crosses the placenta with minimal inactivation.

5.3 Clinical studies Summary

Not known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate, Sodium chloride, Boric acid, Water for Injection.

6.2 **Incompatibilities** None

6.3 Shelf life

24 months from the date of manufacture.

6.4 Special precautions for storage

Store at temperature between 15-30 ^{0}C in a

dark place. Do not freeze Keep out of the reach and sight of children.

6.5 Nature and contents of container

OCUTOB-D Sterile Eye Drops available in 5ml White, Opaque Lupolene Vial (plastic dropper bottle) along with printed leaflet into one printed carton.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CENTAUR PHARMACEUTICALS PVT. LTD.

PLANT – I, PLOT NO.3. 5B, 2C, TIVIM INDUSTRIAL ESTATE, KARASWADA, MAPUSA GOA-403526, INDIA.

8. MARKETING AUTHORISATION NUMBER

H2014/20098/302

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/04/2026

10. DATE OF REVISION OF THE TEXT

09/04/2026