

OCUTOB/OCUTOB-D

Composition

Each ml of **OCUTOB Eye Drops** contains:

Tobramycin sulphate equivalent to Tobramycin 0.3% w/v

Each ml of **OCUTOB-D Eye Drops** contains:

Tobramycin sulphate equivalent to Tobramycin 0.3% w/v

Dexamethasone sodium phosphate 0.1% w/v

Pharmacology

OCUTOB/OCUTOB-D 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/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 **OCUTOB/OCUTOB-D** 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/OCUTOB-D is 2-4 times more active against *Pseudomonas* and *Proteus*, including those resistant to gentamicin.

Dexamethasone in **OCUTOB-D** is a potent corticosteroid that suppresses the inflammatory response to a variety of agents.

Indications

OCUTOB is indicated for the treatment of,

- Neonatal conjunctivitis
- Dacryocystitis
- Blepharitis
- Stye
- Post operatively

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

Contraindications

The use of **OCUTOB/OCUTOB-D** is contraindicated in patients with known hypersensitivity to any of the ingredients of the formulation.

The use of **OCUTOB-D** is also contraindicated in epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella and many other viral diseases of the cornea and conjunctiva, mycobacterial infection of the eye and fungal diseases of ocular structures.

Precautions

As with other antibiotic preparations, prolonged use with **OCUTOB/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/OCUTOB-D** occurs, discontinue use.

Use of contact lenses should be discouraged in patients using **OCUTOB/OCUTOB-D**.

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

Pregnancy & Lactation

There are no adequate and well-controlled studies in pregnant women. **OCUTOB/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/OCUTOB-D** is administered to a nursing woman.

Adverse reactions

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.

The reactions due to the steroid component are elevation of intra-ocular pressure and infrequent optic nerve damage, posterior subcapsular cataract formation and delayed wound healing.

Dosage & Administration

The usual recommended dose of **OCUTOB** in mild to moderate cases is 1-2 drops into the affected eye(s) every 4 hours. In severe infections, the usual dose of **OCUTOB** is 2 drops into the eye(s) every hour until there is improvement, following which treatment should be reduced prior to discontinuation.

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.

Presentation

OCUTOB is available in 5 ml lupolen vial

OCUTOB-D is available in a 5 ml lupolen vial