Dexagen T

Dexamethasone & Tobramycin

Sterile Ophthalmic Suspension & Ointment

Presentation

Dexagen T Suspension: Each ml sterile ophthalmic suspension contains Dexamethasone USP 1 mg & Tobramycin USP 3 mg.

Preservative: Benzalkonium Chloride 0.01%.

Dexagen T Ointment: Each gm sterile eye ointment contains Dexamethasone USP 1mg & Tobramycin USP 3 mg.

Pharmacological Action

Like other amino-glycosides, the bactericidal activity of Tobramycin is accomplished by specific inhibition of normal protein synthesis in susceptible bacteria, but at the present time, very little is known about this action. It is thought that inhibition of protein synthesis is due to an action on ribosome that causes bacterial misreading of messenger RNA.

The action of Dexamethasone is to inhibit the phospholipase A₂, the first step in prostaglandin synthesis. Also Dexamethasone inhibits the chemo-tactic infiltration of neutrophils into the site of inflammation. The result is that its anti-inflammatory activity is 25 times greater and its overall therapeutic effectiveness 8-10 times greater than that of hydrocortisone.

Indications

This is indicated for steroid responsive inflammatory ocular conditions (palpebral and bulbar conjunctiva, cornea and anterior segment of the globe) where superficial bacterial ocular infection exists.

It is also indicated in chronic anterior uveitis and corneal injury from chemical radiation or thermal burns, or penetration of foreign bodies.

The use of combination with an anti-infective component is indicated where the risk of superficial ocular infection is high.

Dosage and Application

Dexagen T Suspension: Insert 1 drop into the conjunctival sac 3-5 times per day. During the initial 24 to 48 hours, the dosage may be increased to 1 drop every 2 hours.

Dexagen T Ointment: Apply a small amount into the conjunctival sac(s) up to 3 or 4 times daily. After applying ointment look downward before closing the eye.

Contraindications

Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and many other viral diseases of the cornea and conjunctiva. Mycobacterial infection of the eye. Hypersensitivity to any component of the medication.

Side Effects

The most frequent adverse reactions to topical ocular Tobramycin are hypersensitivity and localized ocular toxicity including lid itching, swelling and conjunctival erythema. This reaction occurs in less than 4% of patients.

The reactions due to the steroid component are; elevation of intraocular pressure with possible development of glaucoma, and infrequent optic nerve damage, posterior sub capsular cataract formation, and delayed wound healing.

Precautions

The possibility of fungal infections of the cornea should be considered after long-term steroid dosing. As like other antibiotic preparations, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super infection occurs, appropriate therapy should be initiated. Cross-sensitivity to other aminoglycoside antibiotics may occur; if hypersensitivity develops with the product, discontinue use and institute appropriate therapy.

Use in Pregnancy and Lactation

There were no adequate and well controlled studies in pregnant women. This ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potent risk to the fetus.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when this ophthalmic suspension is administered to a nursing woman.

Over Dose

Overdose through local administration is not known. In case of accidental oral intake, specific measures to reduce resorption should be taken. There is no specific antidote.

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

Dexagen T Suspension: Each plastic dropper bottle containing 5 ml sterile ophthalmic suspension.

Dexagen T Ointment: Each tube containing 3 gm sterile eye ointment.



