

Dexaflox

Dexamethasone and Ciprofloxacin
Sterile Eye / Ear Drops

Presentation

Dexaflox: Each ml of sterile eye / ear drops contains Dexamethasone USP 1 mg and Ciprofloxacin 3 mg (as Ciprofloxacin Hydrochloride USP).

Preservative: Benzalkonium Chloride 0.01%.

Vehicle: Povidone 2%

Pharmacological Action

Dexamethasone reduces prostaglandin synthesis by inhibiting the enzyme phospholipase A₂. Also, Dexamethasone inhibits the chemotactic infiltration of neutrophils into the site of inflammation.

Ciprofloxacin has in vitro activity against a wide range of gram-negative and gram-positive organisms, possessing the greatest antibacterial activity of all quinolones. The bactericidal action of Ciprofloxacin results from interference with the enzyme DNA gyrase which is needed for the synthesis of bacterial DNA.

Indications

Dexamethasone & Ciprofloxacin is indicated for the treatment of different types of eye and ear disorder

Eye: Acute and chronic keratitis and conjunctivitis of an infectious, allergic but non-viral nature.

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

Post-operative management of cataract, glaucoma & strabismus. The use of combination with an anti-infective component is indicated where the risk of superficial ocular infection is high.

Ear: This combination is indicated for the treatment of Acute Otitis Media, Acute Otitis Externa & other inflammatory conditions of the ear.

Dosage and Administration

Eye: 1 drop into conjunctival sac(s) every four to six hours. During the initial 24 to 48 hours, the dosage may be increased to 1 drop every two hours.

Ear: 6 months & older:

Acute Otitis Media & Acute Otitis Externa : 4 drops into the affected ear twice daily for seven days.

Contraindications

Known hypersensitivity to any ingredient of the product. Herpes simplex and other viral conditions, mycosis, glaucoma, newborn babies, fungal diseases of ocular or auricular structures.

Side Effects

Frequently reported adverse reactions are transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, photophobia, conjunctivitis/keratitis, periocular/facial edema, foreign body sensation, blurred vision, tearing, dryness, and eye pain. Elevation of intraocular pressure with development of glaucoma, and delayed wound healing may rarely occur. Discomfort, pain, or itching in the ear may occur.

Precautions

Prolonged use may result in overgrowth of non-susceptible organisms including fungi; in ocular hypertension, damage to the optic nerve, defects in visual acuity and posterior sub capsular cataract formation may occur. Patients wearing contact lenses must not use the drops during the time the lenses are worn.

Drug Interactions

Specific drug interaction studies have not been conducted. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, enhance the effects of the oral anticoagulant warfarin and its derivatives and have been associated with transient elevations in serum creatinine in patients receiving cyclosporin concomitantly.

Use in Pregnancy and Lactation

Pregnancy: It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mother: It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in human milk. So caution should be exercised when the combination is administered to a nursing woman.

Overdose

Not known & not likely

Storage Conditions

Store in a cool and dry place away from light. Keep out of reach of children. Do not touch the dropper tip since this may contaminate the solution. After one month of the opening do not use the medicine of dropper.

Commercial Pack

Dexaflox: Each plastic dropper bottle containing 5 ml sterile eye / ear drops.

Manufactured by :

 **GENERAL**
Pharmaceuticals Ltd.

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