

Dexagen G

Gatifloxacin & Dexamethasone Phosphate Sterile Eye Drops

Presentation

Dexagen G: Each ml sterile eye drops contains Gatifloxacin 3 mg (as Gatifloxacin Sesquihydrate INN) & Dexamethasone Phosphate 1 mg (as Dexamethasone Sodium Phosphate USP).

Preservative: Benzalkonium Chloride 0.01%

Pharmacological Action

The antibacterial action of Gatifloxacin results from inhibition of DNA gyrase and topoisomerase IV. DNA gyrase is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA. Topoisomerase IV is an enzyme known to play a key role in the partitioning of the chromosomal DNA during bacterial cell division. Through inhibiting this process Gatifloxacin shows bactericidal activity.

The action of Dexamethasone is to inhibit the phospholipase A2, the first step in prostaglandin synthesis. Also, inhibits the chemotactic infiltration of neutrophils into the site of inflammation. Its anti-inflammatory activity is 30 times greater and its overall therapeutic effectiveness 8-10 times greater than that of hydrocortisone. Like other glucocorticoids, it is anti-allergic, anti-exudative and anti-proliferative.

Indications

This is indicated for steroid responsive inflammatory conditions with involvement of bacteria; such as- Blepharitis, Scleritis, Episcleritis, Iritis, Cyclitis, Iridocyclitis, Choroiditis, Optic neuritis and chronic anterior uveitis. Also useful in disciform and interstitial keratitis, allergic corneal marginal ulcers, corneal injury from chemical radiation or thermal burns.

Dosage and Application

Instill 1-2 drops into the conjunctival sac 3 to 4 times daily.

Contraindications

Contraindicated in fungal disease of ocular structures, viral conjunctivitis and hypersensitivity to any of the components of the formulation.

Side Effects

Frequently reported reactions related to Gatifloxacin include chemosis, redness, dry eye, itching, swelling of the eyelid & reduced visual acuity. The reactions due to Dexamethasone are elevation of intraocular pressure, delayed wound healing and posterior subcapsular cataract formation.

Precautions

If the product is used for 10 days or more, intra ocular pressure should be monitored routinely. Prolonged use of steroid may result in glaucoma or other ocular damage. It may exacerbate severity of viral infections. Use cautiously in patients with history of herpes simplex.

Drug Interactions

There may be an interaction between Gatifloxacin and any of the followings:

Antacids (containing aluminum, calcium, and magnesium), digoxin, probenecid, vitamins (containing zinc, calcium, magnesium, or iron). Specific drug interaction studies have not been conducted with Dexamethasone.

Use in Pregnancy and Lactation

In Pregnancy: Because there are no adequate and well-controlled studies in pregnant women, the eye drops should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In Lactation: Gatifloxacin or Dexamethasone has not been measured in human milk, although it can be presumed to be excreted in human milk following topical administration. Caution should be exercised when the combination is administered to a nursing woman.

Pediatric Use: The safety in Pediatric patients has not been established.

Overdose

Overdose through local or accidental oral administration is not likely. An overdose of this medication is unlikely to threaten life.

Storage Conditions

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

Commercial Pack

Dexagen G: Each plastic dropper bottle containing 5 ml sterile eye drops.

Manufactured by:

 **GENERAL**
Pharmaceuticals Ltd.

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