Loteflam G

Loteprednol Etabonate & Gatifloxacin

Sterile ophthalmic suspension

Presentation

Loteflam G: Each ml sterile ophthalmic suspension contains Loteprednol Etabonate INN 5 mg & Gatifloxacin 3 mg (as Gatifloxacin sesquihydrate INN).

Preservative: Benzalkonium Chloride 0.01%

Vehicle: Povidone 2%

Pharmacological Action

Loteprednol is thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

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 show bactericidal activity

Indications

Loteflam G is indicated for steroid-responsive ocular inflammatory conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or risks of bacterial ocular infection exist. Loteflam G is indicated for palpebral and bulbar conjunctivitis, allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, uveitis, corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

Dosage & Application

Apply one or two drops of Loteflam G suspension of conjunctival sac of the affected eyes every four to six hours. During the initial 24 to 48 hours, the dosing may be increased, to every one to two hours. Frequency should be decreased gradually as warranted by improvement in clinical signs.

Contraindications

Loteflam G is contraindicated in most viral diseases of the cornea and conjunctiva and also in mycobacterial infection of the eye and fungal diseases of ocular structures. Also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

Side Effects

Increased intraocular pressure, burning and stinging upon instillation. Vision disorders, itching, lacrimation disorder, photophobia, corneal deposits, ocular discomfort, eyelid disorder, and other unspecified eye disorders.

Precautions

As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

Use in Pregnancy and Lactation

Pregnancy Category C

There are no adequate and well controlled studies in pregnant women. Loteflam G should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when administered to a nursing woman.

Overdose

Overdose through local administration is not known. In case of accidental oral intake, specific measures to reduce resorption should be taken.

Storage Conditions

Store in a cool (below 30°C) and dry place, away from light. Keep out of the reach of children. Do not touch the dropper tip to surfaces since this may contaminate the suspension. After one month of opening do not use the medicine of dropper.

Commercial Pack

Loteflam G: Each plastic dropper bottle containing 5 ml sterile ophthalmic suspension.

Manufactured by :

general GENERAL Pharmaceuticals Ltd.

Unit-2, Kaliakair, Gazipur, Bangladesh

Revision No. : 01

22060266