

Lotepro™ G Sterile Ophthalmic Suspension

Loteprednol Etabonate 0.5% & Gatifloxacin 0.3%

Presentation

Lotepro™ G Sterile Ophthalmic Suspension: Each ml contains Loteprednol Etabonate INN 5 mg & Gatifloxacin Sesquihydrate INN equivalent to Gatifloxacin 3 mg.

Description

Lotepro™ G is a combination of a topical anti-inflammatory corticosteroid, Loteprednol Etabonate & an 8-methoxyfluoroquinolone antibiotic, Gatifloxacin.

Loteprednol etabonate is structurally similar to other corticosteroids. It is highly lipid soluble which enhances its penetration into cells.

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. It appears that the C-8-methoxy moiety contributes to enhanced activity and lower selection of resistant mutants of gram-positive bacteria compared to the nonmethoxy C-8 moiety.

Indications and uses

Loteprednol & gatifloxacin combination is indicated for the treatment of post operative inflammatory conditions of the eye.

Dosage and Administration

Shake the bottle well before use.

Apply one or two drops of this suspension into the conjunctival sac of the affected eye(s) 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. Care should be taken not to discontinue therapy prematurely.

Adverse effects

The adverse events reported with the fixed dose combination were irritation, pain, redness, photophobia, stinging, itching, discharge & blurred vision. Redness was the most commonly observed adverse event occurring in 6% of patients. Itching, discharge, photophobia & blurred vision were seen in less than 2% cases.

Precautions

General: Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

Fungal infections of the cornea are particularly prone to develop coincidentally with long term local steroid application.

Patients with bleeding tendencies: This fixed dose combination should be used with care in patients with known bleeding tendencies, or in patients who are receiving other medications which may prolong bleeding time.

Ability to drive: As this fixed dose combination may cause transient blurring on instillation, the use of hazardous machinery or driving is not recommended unless vision is clear.

Use in Pregnancy and Lactation

Pregnancy: Since there are no adequate and well controlled studies in pregnant women, Gatifloxacin & Loteprednol combination ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: Since many drugs are excreted in human milk, caution should be exercised when Loteprednol & Gatifloxacin combination ophthalmic solution is administered to a nursing woman.

Pediatric use

Safety and efficacy in pediatric patients have not been established.

Geriatric use

Safety and efficacy in geriatric patients have not been established.

Contraindications

Loteprednol and Gatifloxacin as with other ophthalmic conicosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex and also in mycobacterial infection of the eye and fungal diseases of ocular structures. It is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids. It is also contraindicated in patients with a history of hypersensitivity to other quinolones, acetylsalicylic acid and other nonsteroidal anti-inflammatory medicines.

Drug interactions

No information provided.

Overdose

No information provided.


Storage

- Protect from light. Store in cool and dry place
- Keep out of the reach of children
- Do not use more than 4 weeks after opening

Commercial pack

Lotepro™ G Sterile Ophthalmic Suspension: Plastic dropper bottle containing 5 ml Sterile Ophthalmic Suspension.

Manufactured by

 **Incepta Pharmaceuticals Ltd**

Savar, Dhaka, Bangladesh

LTG

V.N.01