LOTEREX G

LOTEPREDNOL ETABONATE INN + GATIFLOXACIN INN

Compositions:
Each ml contains Loteprednol Etabonate INN 5 mg & Gatifloxacin Sesquihydrate INN equivalent to Gatifloxacin 3 mg.

Pharmacology:
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.

Dosage And Administration:
Shake the bottle well before use. Apply one or two drops of this suspension in to 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.

Contraindications:
Loteprednol and Gatifloxacin as with other ophthalmic corticosteraids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simpiex 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 quinlones, acetylsalicylic acid and other nonsteroidal anti-inflammatory medicines.

Warning And Precaution:
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.

Side Effects:
The adverse events reported with the fixed dose combination were irritation, pain, redness, photophobia, stinging, itching, discharge & blurred vision.

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.

Drug Interaction:
No information provided.

Overdosage:
No information provided.

Storage:
Store at room temperature (15ºC-25ºC) & protect from light. Protect from freezing. Keep out of the reach of children. Do not use more than 30 days after opening.

Packing:
Each plastic dropper bottle contains 5 ml sterile ophthalmic suspension.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.