Loteflam

Loteprednol Etabonate
Sterile Ophthalmic Suspension

Presentation

Loteflam: Each ml sterile ophthalmic suspension contains Loteprednol Etabonate INN 5 mg.
Preservative: Benzalkonium Chloride 0.01%.

Pharmacological Action

Loteprednol Etabonate are thought to act by the induction of phospholipase A_2 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 A_2.
Loteprednol Etabonate is structurally similar to other corticosteroids. However the number 20 position Ketone group is absent. It is highly lipid soluble which enhances its penetration into cells. Loteprednol Etabonate is synthesized through structural modifications of prednisolone-related compounds so that it will undergo a predictable transformation to an inactive metabolite. Based upon in vivo and in vitro preclinical metabolism studies, Loteprednol Etabonate undergoes extensive metabolism to inactive carboxylic acid metabolites.

Indications

Loteflam is indicated for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitides, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.
Loteflam is also indicated for the treatment of post-operative inflammation following ocular surgery.

Dosage and Application

Steroid Responsive Disease Treatment: Apply one to two drops of Loteprednol Etabonate into the conjunctival sac of the affected eye(s) four times daily. During the initial treatment within the first week, the dosing may be increased, up to 1 drop every hour, if necessary.
Post-Operative Inflammation: Apply one to two drops of Loteprednol Etabonate into the conjunctival sac of the operated eye(s) four times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the post-operative period.

Contraindications

Loteprednol Etabonate, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. Loteprednol Etabonate is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

Side Effects

The most common eye-related side effects are Abnormal vision/blurred vision ,Burning, Chemosis (swelling of the conjuctiva), Discharge, Dry eyes, Epiphora (overflow of tears), Foreign body sensation, Itching, Redness, Photophobia (hypersensitivity to light). (Occurring in 5-15% of treated patients

Precautions

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior sub capsular cataract formation. Steroids should be used with caution in the presence of glaucoma.

Drug Interactions

There is no evidence of drug interactions .

Use in Pregnancy and Lactation

Pregnancy Category C. Caution should be exercised when Loteprednol Etabonate is administered to a nursing woman.

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 suspension. After one month of the opening do not use the medicine of dropper.

Commercial Pack

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

Manufactured by :
general GENERAL Pharmaceuticals Ltd.
Unit-2, Gazipur, Bangladesh

GENERAL Pharmaceuticals Ltd. ISO 9001:2008 Certified Company

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