Prescription Only

Lotenol

Loteprednol Etabonate 0.5%

Sterile Eye Ointment

Description
Lotenol is a sterile eye ointment containing Loteprednol Etabonate - a corticosteroid for topical administration to the eyes.

Composition
Each gram contains: Active Substance: Loteprednol Etabonate INN 5 mg

Clinical Pharmacology
Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen and scar formation associated with inflammation. There is no generally accepted explanation for the mechanism of action of ocular corticosteroids. However, corticosteroids 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 the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.

Indications
Lotenol 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, uveitis.

Lotenol is also indicated for the treatment of post-operative inflammation and pain following ocular surgery.

Dosage and Administration
Apply a small amount (Approximately 1/2 inch ribbon) into conjunctival sac(s) four times daily begining 24 hours after surgery and continuing throughout the first 2 weeks of the postoperative period.

Contraindications
Lotenol, 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. It is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

Side Effects
Reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex and perforation of the globe where there is thinning of the cornea or sclera. Ocular adverse reactions occurring in 5%-15% of patients treated with Loteprednol Etabonate sterile ophthalmic suspension. (0.2% - 0.5%) in clinical studies included abnormal vision/blurring, burning on instillation, chemosis, discharge, dry eyes, epiphora, foreign body sensation, itching, injection and photophobia. Other ocular adverse reactions occurring in less than 5% of patients include conjunctivitis, corneal abnormalities, eyelid erythema, keratoconjunctivitis, ocular irritation/pain/discomfort, papillae. Non-ocular adverse reactions occurred in less than 15% of patients. These include headache, rhinitis and pharyngitis.

Precautions
If signs and symptoms fail to improve after two days, the patient should be re-evaluated. If this product is used for 10 days or longer, intraocular pressure should be monitored. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. If redness or itching becomes aggravated, the patient should be advised to consult a physician. Patients should also be advised not to wear contact lenses during their course of therapy.

Use in Pregnancy & Lactation
Pregnancy: Pregnancy Category C. For Loteprednol Etabonate sterile eye ointment no clinical data on exposed pregnancies are available. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown and it should not be used in pregnancy unless clearly necessary.

Lactation: It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Caution should be exercised when Lotenol is administered to a nursing woman.

Drug Interactions
Since Loteprednol Etabonate is not detected in plasma following the topical administration, it is not expected to affect the pharmacokinetics of systemically administered medicinal products.

Overdosage
No case of overdose has been reported.

Pharmaceutical Precautions
Store at below 30°C in a dry place protected from light. Do not touch tube tip to any surface. It is desirable that the contents should not be used one month after first opening of the tube. Protect from freezing.

Commercial Pack
Lotenol Ointment: Each tube contains 3g sterile eye ointment.

Manufactured for:

POPULAR

POPULAR PHARMACEUTICALS LTD.
164, TONGI INDUSTRIAL AREA, GAZIPUR, BANGLADESH

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