Lacrison®

Loteprednol Etabonate 0.5%
Eye Drops

Description

Lacrison® eye drops suspension is a sterile topical anti-inflammatory corticosteroid for ophthalmic use. It 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 the release of their common precursor arachidonic acid.

Indications

Lacrison® eye drops suspension 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, and selected infective conjunctivitis. It is also indicated for the treatment of post-operative inflammation following ocular surgery.

Dosage

SHAKE WELL BEFORE USE.

Steroid Responsive Disease Treatment: Apply 1 to 2 drops of Loteprednol ophthalmic suspension 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 1 to 2 drops of Loteprednol ophthalmic suspension 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.

Side Effects

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.

Contraindications

It 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.

Warning

For topical ophthalmic use only. Not for injection or oral use.

Precaution

The initial prescription and renewal of the medication order beyond 14 days should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

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 even though it may be difficult in children and uncooperative patients.

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.

High Risk Group

Pregnancy:

Teratogenic effects: Pregnancy Category C.

Nursing Mothers: It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemic steroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when Loteprednol is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Drug Interactions

No information available.

Pharmaceutical Precautions

Store in a cool and dry place, away from light. Keep out of reach of children.

Commercial Pack

Lacrison® Eye drops: Plastic dropper bottle of 5 ml sterile suspension. Each ml contains Loteprednol Etabonate 5 mg.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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