Lotrel®

Loteprednol Etabonate INN
Sterile Ophthalmic Suspension

DESCRIPTIONS

Loteprednol is 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 is structurally similar to other corticosteroids. However, the 20 position ketone group is absent. It is highly lipid soluble which enhances its penetration into cells. Loteprednol is synthesized through structural modifications of prednisolone-related compounds. Benzalkonium Chloride 0.01% is used as preservative. Povidone 2% is used as vehicle.

INDICATIONS

Lotrel® 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.

Loteprednol Etabonate is also indicated for the treatment of post-operative inflammation following ocular surgery.

DOSAGE & APPLICATION

Usual Dose: Instill 1 to 2 drops into the conjunctival sac of the affected eye(s) 4 times daily. Within the first week, the dosing may be increased up to 1 drop every hour if necessary.

Usual Dose for Postoperative Ocular Inflammation: Instill 1 to 2 drops into the conjunctival sac of the operated eye(s) 4 times daily beginning 24 hours after surgery. Duration of therapy: Continue for two weeks postoperatively.

CONTRAINDICATIONS

Contraindicated in most viral diseases of the cornea and conjunctiva and also in mycobacterial infection and fungal diseases of ocular structures. Also contraindicated in individuals with known hypersensitivity to Loteprednol Etabonate.

SIDE EFFECTS

Increased intraocular pressure, burning and stinging upon instillation. Vision disorders, itching, lacrimation disorder, photophobia, corneal deposits, ocular discomfort, eyelid disorder, and other unspecified eye disorders.

PRECAUTIONS

If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated. If this product is used for 10 days or longer, intraocular pressure should be monitored.

USE IN PREGNANCY & LACTATION

Pregnancy Category C

There are no adequate and well controlled studies in pregnant women. **Lotrel®** should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when administered to a nursing woman.

PHARMACEUTICAL PRECAUTION

Store in a dry place and away from light. Keep out of reach of children. Store in an upright position. To prevent contamination of the dropper tip and suspension, care should be taken. Don't touch the eyelids, surrounding areas, finger or other surfaces with the dropper tip of the bottle. The bottle should be tightly closed when not in use. Do not use after 4 weeks of first opening.

PACKAGING

Lotrel® Ophthalmic Suspension: Each plastic dropper bottle containing 5 mL sterile ophthalmic suspension. Each mL contains Loteprednol Etabonate INN 5 mg.

SK+F
Manufactured by
ESKAYEF BANGLADESH LIMITED
GAZIPUR, BANGLADESH
® REGD. TRADEMARK
PM03520 V02