Loteflam T

Loteprednol Etabonate & Tobramycin
Sterile Ophthalmic Suspension

Presentation

Loteflam T: Each ml sterile ophthalmic suspension contains Loteprednol Etabonate INN 5 mg & Tobramycin USP 3 mg.

Preservative: Benzalkonium Chloride 0.01%

Vehicle: Povidone 2%

Pharmacological Action

Loteprednol 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 release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2. Loteprednol 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. Like other amino glycosides the bactericidal activity of tobramycin is taken up into sensitive bacterial cells by an active transport process. Within the cell tobramycin bind to 30s and to some extent to the 50s subunits of the bacterial ribosome, inhibiting protein synthesis and generating errors in the transcription of the genetic code.

Indications

Loteflam T is indicated for steroid-responsive ocular inflammatory conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

- Palpebral and bulbar conjunctivitis
- Allergic conjunctivitis
- Acne rosacea
- Superficial punctate keratitis
- Herpes zoster keratitis
- Iritis
- Cyclitis
- Uveitis
- Corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

The use of combination with an anti-infective component is indicated where the risk of superficial ocular infection is high.

Dosage & Application

Apply one or two drops into 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.

Contraindications

Loteflam T is contraindicated in most viral diseases of the cornea and conjunctiva and also in mycobacterial infection of the eye and fungal diseases of ocular structures. Also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

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 and Lactation

Pregnancy Category C

There are no adequate and well controlled studies in pregnant women. Loteflam T 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.

Over Dosage

Overdose through local administration is not known. In case of accidental oral intake, specific measures to reduce resorption should be taken.

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 first opening, do not use the medicine of dropper.

Commercial Pack

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

Manufactured by :

GENERAL Pharmaceuticals Ltd.
Unit-2, Gazipur, Bangladesh

GENERAL Pharmaceuticals Ltd.
ISO 9001:2008 Certified Company

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