

Lotepred[®]

Loteprednol Etabonate 0.5%
Ophthalmic Suspension

Composition:

Lotepred[®] Ophthalmic Suspension: Each ml contains Loteprednol Etabonate INN 5 mg.

Preservative: Sodium Perborate BP 0.02%.

Vehicle: Povidone BP 0.6%.

Pharmacology:

Loteprednol is a corticosteroid which is thought to act by the induction of phospholipase A2 inhibitory proteins, which control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid.

Indications:

Lotepred[®] is indicated in steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of eyeball such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis & cyclitis. It is also effective in post-operative inflammation.

Dosage & administration:

For steroid responsive ocular inflammation: Instill 1 drop of **Lotepred[®]** Ophthalmic Suspension into the conjunctival sac of the eye(s) four times a day.

For inflammation after surgery: Instill 1 drop of **Lotepred[®]** Ophthalmic Suspension into the conjunctival sac of the operated eye(s) four times a day beginning 24 hours after surgery and continuing throughout the first two weeks after surgery.

Contraindications:

It is contraindicated in most viral diseases of the cornea and conjunctiva. 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:

Glaucoma with optic nerve damage, visual acuity and field defects; cataract formation; secondary ocular infection following suppression of host response; and perforation of the globe may occur.

Precautions:

- ◆ For ophthalmic use only.
- ◆ If this product is used for 10 days or longer, intraocular pressure should be monitored.
- ◆ Fungal infections of the cornea are particularly prone to develop coincidentally with long-term use of steroid topically.
- ◆ Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and visual field, and in posterior subcapsular cataract formation.
- ◆ Use of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution.
- ◆ Patients wearing contact lenses must not use the drops during the time the lenses are worn.

Use in pregnancy:

No clinical data available.

Use in lactation:

It is not known whether Loteprednol Etabonate passes into breast milk.

Use in children:

Safety and effectiveness in pediatric patients have not been established.

Storage:

- ◆ Store below 30°C temperature in a dry place, protect from light.
- ◆ Do not use longer than 30 days after first opening.
- ◆ Keep out of the reach of children.

Packing:

Lotepred[®] Ophthalmic Suspension : Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.

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Manufactured by:
ARISTOPHARMA LTD.
GAZIPUR, BANGLADESH