

# Lotepred Gel

Loteprednol Etabonate INN 0.5%  
Ophthalmic Gel

**Composition:**

**Lotepred Gel Ophthalmic Gel:** Each gm gel contains Loteprednol Etabonate INN 5 mg.

**Preservative:**

Sodium Perborate BP 0.01%

**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 Gel is indicated for the treatment of post-operative inflammation and pain following ocular surgery. It is also effective 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

**Dosage & administration:**

Instill one to two drops of Lotepred Gel Ophthalmic Gel into the conjunctival sac of the affected eye four times daily beginning the day after surgery and continuing throughout the first 2 weeks of the postoperative period.

**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.

**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.

**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 in a cool & dry place, protect from light.
- ◆ Store between 15°-25°C.
- ◆ Discard 30 days after opening.
- ◆ Keep out of the reach of children.

**Packing:**

**Lotepred Gel Ophthalmic Gel:** Each tube contains 5 gm sterile ophthalmic gel.



Manufactured by:  
**ARISTOPHARMA LTD.**  
SHAMPUR-DHAKA-BANGLADESH

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