# Information For the Use Loteprednol etabonate (0.5% w/v)

## **Lotprod Eye Drop**

Loteprednol Etabonate (0.5% w/v) Eye Drops

Category: Corticosteroid (Ophthalmic)
Dosage Form: Sterile ophthalmic suspension

## **Description**

Loteprednol Etabonate is a topical corticosteroid with strong anti-inflammatory properties, designed for use in ophthalmology. Its unique "soft steroid" profile ensures effective treatment of ocular inflammation with reduced risk of systemic and ocular side effects.

## **Composition (Per mL):**

• Loteprednol Etabonate: 0.5% w/v

#### **Indications**

- 1. Ocular Inflammation and Pain:
  - Post-operative inflammation following cataract or other ocular surgeries.
- 2. Seasonal Allergic Conjunctivitis:
  - Reduces redness, swelling, and itching.
- 3. Anterior Uveitis:
  - Effective in treating inflammation of the anterior segment of the eye.
- 4. Chronic or Acute Non-Infectious Ocular Inflammation:
  - Includes conditions like iritis, episcleritis, or keratitis (noninfectious).

• Instill 1–2 drops in the affected eye(s) 4 times daily, or as prescribed by a healthcare professional.

 In severe cases, the frequency may be increased during the first 24–48 hours.

#### **Instructions for Use:**

- 1. Wash hands thoroughly before using the drops.
- 2. Shake the bottle well.
- 3. Tilt the head back, pull down the lower eyelid, and instill drops into the conjunctival sac.
- 4. Avoid touching the dropper tip to any surface to prevent contamination.

#### **Mechanism of Action**

## **Loteprednol Etabonate acts by:**

- 1. Inhibiting Inflammatory Mediators:
  - Blocks the production of prostaglandins and leukotrienes by suppressing phospholipase A2 and the arachidonic acid pathway.
- 2. Reducing Cellular Infiltration:
  - Minimizes immune cell migration to inflamed tissues.

#### **Pharmacokinetics**

- Low Systemic Absorption: Loteprednol undergoes rapid metabolic deactivation in the eye, minimizing systemic side effects.
- Targeted Ocular Action: High local efficacy in managing inflammation.

#### **Dosage and Administration**

Adults and Children (Above 2 Years):

**Contraindications** 

- Viral infections of the cornea and conjunctiva (e.g., herpes simplex keratitis).
- Mycobacterial, fungal, or untreated bacterial infections of the eye.
- Hypersensitivity to Loteprednol or any of its components.

## **Warnings and Precautions**

- 1. Prolonged Use:
  - May increase intraocular pressure (IOP), potentially causing glaucoma.
  - Risk of posterior subcapsular cataracts with extended use.
- 2. Infections:
  - Corticosteroids can mask symptoms of infection or worsen existing infections.
- 3. Pregnancy and Lactation:
  - Use only if prescribed by a healthcare provider.
- 4. Contact Lenses:
  - Avoid using contact lenses during active inflammation or while on this medication.

#### **Adverse Effects**

#### **Common side effects include:**

- Temporary burning or stinging sensation.
- Blurred vision or discomfort immediately after instillation.
- Dryness or redness of the eyes.

### Rare but serious side effects:

- Increased intraocular pressure.
- Secondary infections due to prolonged use.
- Thinning of the cornea or sclera.

- Store at a temperature below 25°C.
- Keep the bottle tightly closed when not in use.
- Protect from light and do not freeze.
- Discard the bottle 4 weeks after opening.

## **Key Points for Use**

- Do not discontinue the medication abruptly without consulting your doctor.
- Regular monitoring of intraocular pressure (IOP) is recommended if used for more than 10 days.
- Report any worsening symptoms, persistent redness, or pain immediately to your healthcare provider.

Note: Use under medical supervision, particularly for children, pregnant women, or individuals with a history of ocular conditions such as glaucoma.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

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