

Tobraxyle LT Eye Drop

**Loteprednol Etabonate (0.5% w/v) +
Tobramycin (0.3% w/v) Eye Drops**

Description

Loteprednol Etabonate (0.5% w/v) + Tobramycin (0.3% w/v) Eye Drops is a combination ophthalmic medication used to treat eye infections and inflammation. It combines the anti-inflammatory corticosteroid Loteprednol Etabonate and the antibiotic Tobramycin, which is effective against bacterial infections. This combination is designed to treat and manage conditions such as ocular inflammation and bacterial conjunctivitis, particularly in patients at risk of infection following ocular surgery or injury.

Composition

Each mL of Loteprednol Etabonate (0.5% w/v) + Tobramycin (0.3% w/v) Eye Drops contains:

- **Loteprednol Etabonate: 5 mg (0.5% w/v)**
 - **Tobramycin: 3 mg (0.3% w/v)**
 - **Other ingredients:** Preservatives and excipients such as benzalkonium chloride (for preservation), sodium chloride, hydrochloric acid, and water for injection.
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Indications

This eye drop combination is indicated for the treatment of:

- **Ocular inflammation associated with steroid-responsive inflammatory conditions, such as uveitis or post-surgical inflammation.**

- **Bacterial eye infections, such as conjunctivitis and blepharitis, caused by susceptible Gram-positive and Gram-negative bacteria.**
 - **Prophylaxis of infection and inflammation following ocular surgery or trauma.**
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Mechanism of Action

- **Loteprednol Etabonate:** A corticosteroid that reduces inflammation by inhibiting the release of pro-inflammatory mediators such as prostaglandins, leukotrienes, and cytokines. This helps decrease swelling, redness, and irritation in the eye.
 - **Tobramycin:** An aminoglycoside antibiotic that works by binding to bacterial ribosomes, disrupting protein synthesis and preventing bacterial growth. It is effective against a variety of Gram-positive and Gram-negative organisms, including those commonly responsible for eye infections.
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Dosage and Administration

- **Adult and Pediatric Dosage (age ≥ 2 years):**
 - **Initial Dose:** Place 1-2 drops into the affected eye(s) every 4 to 6 hours for the first few days of treatment.
 - **Maintenance Dose:** Once the condition improves, the dosage can be reduced to 1 drop every 6 to 8 hours, as directed by the healthcare provider.
- **Post-Surgical Dosage:** After eye surgery, the recommended dose is 1 drop in the affected eye 3 to 4 times daily for the first 2 weeks, followed by a gradual reduction

in frequency based on the doctor's recommendation.

- **Method of Administration:**
 - Wash your hands before using the eye drops.
 - Tilt your head back slightly and pull down the lower eyelid to form a pocket.
 - Squeeze the bottle to release the prescribed number of drops into the eye.
 - Close your eyes gently and press the inner corner of the eye (near the nose) to prevent the medication from draining into the tear duct.
 - Do not touch the dropper tip to any surface, including your eye, to avoid contamination.
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Contraindications

- Hypersensitivity to Loteprednol Etabonate, Tobramycin, or any other component of the formulation.
 - Viral infections of the eye, such as herpes simplex keratitis or varicella, as corticosteroids like Loteprednol can exacerbate these conditions.
 - Fungal infections or mycobacterial infections of the eye.
 - Uncontrolled glaucoma (elevated intraocular pressure) in patients using the medication for an extended period.
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Warnings and Precautions

- **Prolonged Use:** Prolonged use of corticosteroids can increase the risk of ocular hypertension, glaucoma, and cataract formation. Eye pressure should be monitored regularly during prolonged treatment.
- **Infections:** Prolonged use of corticosteroids can suppress the immune response, making the eye more susceptible to infections. If a new infection occurs, discontinue the

medication and treat with an appropriate antibiotic.

- **Corneal Healing:** Use with caution in patients with corneal epithelial defects or those who have recently had corneal surgery, as steroids can delay healing.
 - **Contact Lenses:** Avoid using the medication while wearing contact lenses, as the preservative in the drops can accumulate in the lens material. Remove contact lenses before instilling the drops and wait at least 15 minutes before reinserting them.
 - **Pregnancy and Lactation:** The safety of this eye drop during pregnancy and lactation has not been fully established. Use only if the benefits outweigh the potential risks. Consult a healthcare provider before use during pregnancy or breastfeeding.
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Side Effects

Common side effects may include:

- Eye irritation, such as burning, stinging, or a foreign body sensation.
- Temporary blurred vision upon instillation.
- Redness or dryness in the eye.

Serious side effects include:

- Increased intraocular pressure (possible glaucoma).
- Cataract formation with prolonged use.
- Infection or worsening of existing eye infections.
- Allergic reactions including swelling, itching, or rash around the eye.
- Vision changes such as blurred or double vision.

If you experience any of these side effects or other unusual symptoms, contact your healthcare provider immediately.

Drug Interactions

- **Other topical ocular medications:** If you are using other eye drops, wait at least 5 minutes before applying this product.
 - **Systemic corticosteroids:** Concurrent use with systemic corticosteroids may increase the risk of increased intraocular pressure or cataracts.
 - **Immunosuppressants:** Concurrent use with immunosuppressive drugs may increase the risk of infection.
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Storage Instructions

- **Store the bottle tightly closed at room temperature (15°C to 25°C).**
 - **Keep the bottle away from light and heat.**
 - **Do not freeze.**
 - **Keep out of reach of children.**
 - **Discard the bottle 28 days after opening, even if there is remaining solution.**
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Presentation

- **Form:** Ophthalmic solution (eye drops)
 - **Strength:** 0.5% Loteprednol Etabonate + 0.3% Tobramycin
 - **Pack Size:** Available in 5 mL or 10 mL bottles with a dropper for easy administration.
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Conclusion

Loteprednol Etabonate (0.5% w/v) + Tobramycin (0.3% w/v) Eye Drops is an effective combination therapy for managing eye inflammation and bacterial infections. It is essential to use this medication according to the prescribed dosage and for the recommended duration to avoid complications such as increased intraocular pressure, cataracts, and the potential for infection. Regular monitoring by a healthcare provider is advised, especially with prolonged use, and patients should follow

proper hygiene practices when administering the drops.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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