

**Clinical Studies**

Post-Operative Inflammation: Placebo-controlled clinical studies demonstrated that LOTEMAX is effective for the treatment of anterior chamber inflammation as measured by cell and flare.

GIuant Purulent Conjunctivitis: Placebo-controlled clinical studies demonstrated that LOTEMAX was effective in reducing the signs and symptoms of gram-positive conjunctivitis after 1 week of treatment and continuing for up to 6 weeks while on treatment.

Seasonal Allergic Conjunctivitis: A placebo-controlled clinical study demonstrated that LOTEMAX was effective in reducing the signs and symptoms of allergic conjunctivitis during peak periods of pollen exposure.

Events: Controlled clinical studies of patients with uveitis demonstrated that LOTEMAX was less effective than prednisolone acetate 1%. Overall, 72% of patients treated with LOTEMAX experienced resolution of anterior chamber cells, compared to 87% of patients treated with prednisolone acetate 1%. The incidence of patients with clinically significant increases in IOP (>10 mmHg) was 1% with LOTEMAX and 6% with prednisolone acetate 1%.

**INDICATIONS AND USAGE**

LOTEMAX is also indicated for the treatment of post-operative inflammation following ocular surgery.

**CONTRAINDICATIONS**

LOTEMAX, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. LOTEMAX is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

**WARNINGS**

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Steroids should be used with caution in the presence of glaucoma.

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Use of ocular steroids may prolong the course and may exacerbate the severity of any viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution.

**PRESERVATIVE ADDED:** Benzyalkonium Chloride 0.01%.

**CLINICAL PHARMACOLOGY**

Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the edema, fibrosis, deposition, collagen, migration, proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. There is no generally accepted explanation for the mechanism of action of ocular corticosteroids. However, corticosteroids are thought to act by the induction of phospholipase A, inhibiting proteins, collectively called lipoxygenases. It is postulated that these proteins control the synthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A. Corticosteroids are capable of producing a rise in intraocular pressure (IOP).

Loteprednol etabonate is structurally similar to other corticosteroids. However, the number 20 position ketone group is absent. It is hydrolytically unstable which enhances its penetration into cells. Loteprednol etabonate is synthesized through structural modifications of prednisolone-related compounds so that it will undergo a predictable transformation to an inactive metabolite. Based upon in vivo and in vitro preclinical metabolism studies, loteprednol etabonate undergoes extensive metabolism to inactive carboxylic acid metabolites. Results from a bioavailability study in normal volunteers established that plasma levels of loteprednol etabonate and its carboxylic acid ester (FP 919), its primary, inactive metabolite, were below the limit of quantitation (1 ng/mL) at all sampling times. The results were obtained following the oral administration of one drop in each eye of 0.5% loteprednol etabonate 8 times daily for 2 days or 4 times daily for 42 days. This study suggests that limited (<1 ng/mL) systemic absorption occurs with LOTEMAX.

Loteprednol etabonate is a white to off-white powder. The suspension is essentially isotonic with a tonicity of 250 to 310 mOsmol/kg.

LOTEMAX is a sterile, topical anti-inflammatory corticosteroid for ophthalmic use.

Chemical Name: chloromethyl 17α-[ethoxycarbonyl]oxy]-11β-hydroxy-3-oxandrost-1,4-diene-17β-carboxylate.

Each mL contains:

- ACTIVE: Loteprednol Etabonate 5 mg (0.5%);
- INERT: Sodium Chloride, Purified Water and Triethylglycol. Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust the pH. The suspension is essentially isotonic with a tonicity of 250 to 310 mOsmol/kg.

**PRECAUTIONS**

For ophthalmic use only. The initial prescription and renewal of the medication order beyond 14 days should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

If signs and symptoms fail to improve after 1 week, the patient should be re-evaluated.

If this product is used for 10 days or longer, intraocular pressure should be monitored even though it may be difficult in children and uncomplicated patients (see WARNINGS).

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.

**Information for Patients**

This product is sterile when packaged. Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the suspension. If pain develops, redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician. As with all ophthalmic preparations containing benzalkonium chloride, patients should be advised not to wear soft contact lenses when using LOTEMAX suspension.
# LOTE MAX

## HOW SUPPLIED

LOTEMAX (loteprednol etabonate ophthalmic suspension) is supplied in a plastic bottle with a controlled drop tip in the following sizes:

- **15 mL** (NDC 24208-299-15)
- **10 mL** (NDC 24208-299-10)
- **5 mL** (NDC 24208-299-05)

## ADVERSE REACTIONS

### Ocular Adverse Reactions

- **Common:** Occurs in more than 1/10 patients treated with LOTE MAX.
- **Uncommon:** Occurs in 1/10 to 1/100 patients treated with LOTE MAX.
- **Rare:** Occurs in less than 1/100 patients treated with LOTE MAX.

### Non-ocular Adverse Reactions

- **Common:** Occurs in more than 1/10 patients treated with LOTE MAX.
- **Uncommon:** Occurs in 1/10 to 1/100 patients treated with LOTE MAX.
- **Rare:** Occurs in less than 1/100 patients treated with LOTE MAX.

### Contraindications

- **ALLERGIC REACTIONS TO LOTEMAX OR ITS INGREDIENTS.
- **SEROUS OCULAR EFFUSION OR INFUNDIBULAR BLOCK.
- **ACUTE ANGINA PECTORIS.
- **DEVELOPMENTAL DYSTROPHIC EYEBALL.
- **INFLAMMATORY BLEEDING PHENOMENA.
- **ACUTE BILATERAL GLAUCOMA.
- **OCULAR INJURY OR SURGERY.
- **ACUTE ANTIBODY-INDUCED SYMPATHETIC OPTIC NEURITIS.
- **INTRAOCULAR PRESSURE INCREASED TO LEVELS SUPERIOR TO 34 MM Hg.
- **PREGNANCY:** Pregnant women should not use LOTE MAX.
- **LACTATION:** It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemic steroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when LOTEMAX is administered to a nursing woman.

### PRECAUTIONS

- **DILATED PUPILS:** Patients should not drive or operate hazardous machinery during the initial treatment period, as the pupils may remain dilated for two days or longer.
- **STORAGE:** Store upright between 15° to 25°C (59° to 77°F). Do not freeze.
- **DO NOT USE IF NECKBAND IMPRINTED WITH “Protective Seal” AND YELLOW IS NOT INTACT.

### DISTRIBUTED BY

- **Bausch + Lomb Incorporated:** 1-800-321-4576 or www.fda.gov/medwatch.

### REVISIONS

- **2020 Bausch & Lomb Incorporated or its affiliates**
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