LOTEMAX® ointment is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.  

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**INDICATIONS AND USAGE**

LOTEMAX® ointment is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

**DOSE AND ADMINISTRATION**

Apply a small amount (approximately 1/8 inch ribbon) into the conjunctival sac(s) four times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the post-operative period.

**DOSE FORMS AND STRENGTHS**

3.5 gram tube filled with loteprednol etabonate ophthalmic ointment, 0.5%.

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**WARNINGS AND PRECAUTIONS**

- **Systemic and Local Adverse Effects**
  - Cataracts–Use of corticosteroids may result in posterior subcapsular cataract formation (5.2)
  - Systemic, corticosteroid-induced diabetes, hypertension, and peptic ulceration

**CONTRAINDICATIONS**

LOTEMAX® ointment, 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. (4)

**ADVERSE REACTIONS**

Adverse reactions associated with ophthalmic steroids include delayed healing. The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids (5.3).

**Bacterial Infections**

- Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored even though it may be difficult in children and uncooperative patients. (5.1)

**Fungal Infections**

- Fungal infections–Fungal infections of the cornea are particularly prone to develop coincidently with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration that has been treated with topical steroids. (5.3)

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Loteprednol etabonate is a white to off-white powder. Loteprednol etabonate is a sterile, topical corticosteroid for ophthalmic use. Loteprednol etabonate is not expected to exceed exposures attained with LOTEMAX (loteprednol etabonate ophthalmic ointment) 0.5% administration of the ointment product dosed four times daily for 12 days. The maximum systemic exposure to loteprednol following oral administration of one drop in each eye of 0.5% loteprednol etabonate suspension (5 times daily for 2 days or 4 times daily for 42 days. The maximum systemic exposure to loteprednol following administration of the ointment product dosed four times daily is not expected to exceed exposures attained with LOTEMAX suspension dosed up to two drops four times daily.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate. Loteprednol etabonate was not genotoxic in the Ames test, the mouse lymphoma tk assay, or in a chromosome aberration test in human lymphocytes, or in the single dose mouse microneedle assay. Treatment of males and females rats with up to 50 mg/kg/day and 25 mg/kg/day of loteprednol etabonate, respectively, for 12 and 50 times the maximum daily clinical dose, respectively, prior to and during mating did not impair fertility in either gender.

14 CLINICAL STUDIES

In two independent, randomized, multicenter, double-masked, parallel-group, vehicle-controlled studies in BOS subjects meeting a protocol-specified threshold amount of anterior chamber inflammation, LOTEMAX ointment was more effective compared to its vehicle for complete resolution of post-operative anterior chamber inflammation, and pain following cataract surgery. Primary endpoint was complete resolution of anterior chamber cells and flare (cell count of 0 and no flare) and no pain at post-operative day 8. The individual clinical trial results are provided below.

In the 2 studies, Lotemax had statistically significant higher incidence of complete clearing of anterior chamber cells and flare at post-operative day 8 (24-28% vs. 11-14%) and also had a statistically significant higher incidence of subjects who were pain free at post-operative day 8 (73-78% vs. 40-45%).

16 HOW SUPPLIED/STORAGE AND HANDLING

LOTEMAX (loteprednol etabonate ophthalmic ointment), 0.5% is a sterile ointment supplied as a tube with a pink polypropylene cap in the following sizes: 3.5 gram (NDC 24208-443-35).

Do not use if tamper evident skirt is visible on bottom of cap.


Rx only.

17 PATIENT COUNSELING INFORMATION

17.1 Risk of Contamination

Patients should be advised not to touch the eyelid or surrounding areas with the tip of the tube. The cap should remain on the tube when not in use. Patients should be advised to wash hands prior to using LOTEMAX ointment.

Do not use if tamper evident skirt is visible on bottom of cap.

17.2 Contact Lens Wear

Patients should also be advised not to wear contact lenses during their course of therapy.

17.3 Risk of Secondary Infection

If redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician.

MANUFACTURER INFORMATION

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