Lometam (loteprednol etabonate ophthalmic ointment) 0.5%

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use this product safely and effectively. See full prescribing information for LOMETAM ointment.

LOMETAM® (loteprednol etabonate ophthalmic ointment) 0.5% Initial U.S. Approval: 1998

INDICATIONS AND USAGE
LOMETAM ointment is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery. (1)

Dosage and Administration
Apply a small amount (approximately 0.5 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. (2)

DOSAGE FORMS AND STRENGTHS
Ointment, 3.5 g tube filled with loteprednol etabonate ophthalmic ointment, 0.5%. (3)

CONTRAINDICATIONS
Ointment, 3.5 g tube filled with loteprednol etabonate ophthalmic ointment, 0.5%. (5.3)

WARNINGS AND PRECAUTIONS

INTRAOCULAR PRESSURE INCREASE
• Intraocular Pressure (IOP) Increase—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)

CATARACTS—Use of corticosteroids may result in posterior subcapsular cataract formation. (5.2)

TOPICAL OPHTHALMIC USE ONLY

ADVERSE REACTIONS

INFORMATION FOR CONSUMERS

The most common ocular adverse event, reported in approximately 25% of subjects in clinical studies, is anterior chamber inflammation. Other common adverse events, with an incidence of 4-5%, are conjunctival hyperemia, corneal edema, and eye pain. (5.4)

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In the treatment of postoperative inflammation or sclera, perforations have been known to occur with the use of topical steroids. (5.3)

Bacterial Infections—Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. (5.5)

Fungal Infections—Fungal infections of the cornea are particularly prone to develop coincidentally with long-term topical steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. (5.6)

To report SUSPECTED ADVERSE REACTIONS, contact Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Sea 17 for PATIENT COUNSELING INFORMATION.

Revised: 11/2017

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In acute purulent conditions, steroids may mask infection or enhance existing infection if the infections fail to improve after 2 days, the patient should be re-evaluated. (5.5)

Application of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). (5.5)

Fungal Infections—Fungal infections of the cornea are particularly prone to develop coincidentally with long-term topical steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. (5.6)

Patients should not wear contact lenses during their course of therapy with LOMETAM ointment. (5.7)

Amblyopia

LOMETAM (loteprednol etabonate ophthalmic ointment), 0.5% should not be used in children following ocular surgery. Its use may interfere with amblyopia treatment by hindering the child’s ability to see out of the operated eye [see Use in Specific Populations, (8.1)]

Topical Ophthalmic Use Only

Lometam is not indicated for intracocular administration. (5.9)

ADVERSE REACTIONS

Adverse reactions associated with ophthalmic steroids include eye irritation, burning, stinging, redness, conjunctival hyperemia, allergic sensitization, allergy, changes in ocular color, itching of the eye, conjunctival hyperemia, corneal edema, and eye pain. Many of these events may have been the consequence of the surgical procedure. The only non-ocular adverse event occurring at ≥1% was headache (1.5%).

Other common adverse events, with an incidence of 4-5%, are conjunctival hyperemia, corneal edema, and eye pain. (5.4)

The use of steroid after cataract surgery may delay healing and increase the incidence of bleb formation. In the treatment of postoperative inflammation or sclera, perforations have been known to occur with the use of topical steroids. (5.3)

Bacterial Infections—Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. (5.5)

Fungal Infections—Fungal infections of the cornea are particularly prone to develop coincidentally with long-term topical steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. (5.6)

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THE USE OF STEROIDS AFTER CATARACT SURGERY MAY DELAY HEALING AND INCREASE THE INCIDENCE OF BLEB FORMATION. IN THE TREATMENT OF POSTOPERATIVE INFLAMMATION OR SCLERA, PERFORATIONS HAVE BEEN KNOWN TO OCCUR WITH THE USE OF TOPICAL STEROIDS. (5.3)

OTHER COMMON ADVERSE EVENTS, WITH AN INCIDENCE OF 4-5%, WERE CONJUNCTIVAL HYPEREMIA, CORNEAL EDEMA, AND EYE PAIN. MANY OF THESE EVENTS MAY HAVE BEEN THE CONSEQUENCE OF THE SURGICAL PROCEDURE. THE ONLY NON-Ocular ADVERSE EVENT OCCURRING AT ≥1% WAS HEADACHE (1.5%).
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Teratogenic Effects
Loteprednol etabonate has been shown to be embryotoxic (delayed ossification) and teratogenic (increased incidence of meningocele, abnormal left common carotid artery, and limb flexures) when administered orally to rabbits during organogenesis at a dose of 3 mg/kg/day (500 times the maximum daily clinical dose), a dose which caused no maternal toxicity. The no-observed-effect-level (NOEL) for these effects was 0.5 mg/kg/day (25 times the maximum daily clinical dose). Oral treatment of rats during organogenesis resulted in teratogenicity (absent innominate artery at a dose at 5 mg/kg/day), cleft palate and umbilical hernia at 0.5 mg/kg/day) and embryotoxicity (increased post-implantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossification with <30 mg/kg/day). Treatment of rats with 0.5 mg/kg/day (25 times the maximum daily clinical dose) during organogenesis did not result in any reproductive toxicity. Loteprednol etabonate had no effect on the duration of gestation or parturition when administered orally to pregnant rats at doses up to 50 mg/kg/day during the fetal period. LOTEMAX should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or fetus.

8.3 Nursing Mothers
It is not known whether topical ocular administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many corticosteroids appear in human milk, and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects, caution should be exercised when LOTEMAX ointment is administered to a nursing woman. It is not known whether topical ocular administration of loteprednol etabonate from the start of the fetal period through the end of lactation, a maternally toxic treatment regimen (significantly reduced body weight gain during treatment) when administered to pregnant rats during organogenesis at doses of 0.5 mg/kg/day. Exposure of female rats to 50 mg/kg/day of loteprednol etabonate at the start of the fetal period through the end of lactation; the NOEL for these effects was 5 mg/kg/day. Loteprednol etabonate had no effect on the duration of gestation or parturition when administered orally to pregnant rats at doses up to 50 mg/kg/day during the fetal period.

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