BE PREPARED FOR YOUR EYE SURGERY WITH LOTE MAX® GEL

Use LOTE MAX® GEL treatment after your eye surgery to help:

✔️ REDUCE INFLAMMATION
✔️ RELIEVE PAIN

There is no generic formulation for LOTE MAX® GEL
MAKE SURE YOU RECEIVE BRANDED LOTE MAX® GEL AT THE PHARMACY

Indication
LOTE MAX® GEL (loteprednol etabonate ophthalmic gel) 0.5% is used to treat inflammation and pain following eye surgery.

Important Safety Information
• LOTE MAX® GEL should not be used if you have an infection in your eye.
• Before using LOTE MAX® GEL, turn bottle upside down and shake once to fill the bottle tip. To avoid contamination, do not let dropper touch any surface.

Please see Important Safety Information on pages 1 & 2 and full Prescribing Information on pages 5 & 6.

BAUSCH + LOMB
WHY YOUR DOCTOR CHOSE
LOTEMAX® GEL FOR YOU

Your doctor has prescribed LOTEMAX® GEL after your eye surgery to help treat inflammation and pain. LOTEMAX® GEL offers these important features:

- **GEL formulation designed to stay on your eye**
- **Consistent dosing**
  - No shaking is required
  - With LOTEMAX® GEL, you get the same amount of treatment with every drop, every time
- **Designed with these features**
  - LOTEMAX® GEL includes moisturizing ingredients and has a pH level close to human tears
  - ~70% less preservatives than LOTEMAX® Suspension (loteprednol etabonate ophthalmic suspension) 0.5%

**Important Safety Information (cont’d)**

- Do not wear contact lenses when using LOTEMAX® GEL.
- Contact your doctor if pain develops or if redness, itching or inflammation becomes aggravated.
- If you use LOTEMAX® GEL for longer than 10 days, your doctor may monitor pressure in your eye. Use of medications such as LOTEMAX® GEL may result in cataract formation, or may delay healing after cataract surgery.
- The most common side effects in clinical studies were eye inflammation, eye pain and foreign body sensation.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Important Safety Information on pages 1 & 2 and full Prescribing Information on pages 5 & 6.
LOTEMAX® GEL has **no substitute**

Most eye surgeries are once-in-a-lifetime events to improve your vision. You’ve made this investment because your eyesight is very valuable, and your eye care after surgery is equally important.

Since your doctor has recommended this GEL treatment, it is important to make sure your pharmacist does not switch you to a different, generic formulation.

### Make sure you receive savings at the pharmacy.

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<th>Commercially Insured</th>
<th>Uninsured Patients</th>
<th>Medicare Part D</th>
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<tr>
<td><strong>LOTEMAX® GEL Co-Pay for Eligible Patients</strong></td>
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*Terms and conditions apply. Please see [www.bauschaccessprogram.com](http://www.bauschaccessprogram.com) and [www.lotemaxgelpartdcoupon.com](http://www.lotemaxgelpartdcoupon.com) for eligibility criteria and terms and conditions.*
GET SPECIAL SAVINGS ON
LOTEMAX® GEL

Bausch + Lomb is committed to providing value savings, whether you’re an eligible commercially insured, eligible Medicare Part D, or eligible uninsured patient.

ELIGIBLE COMMERCIAL INSURED & UNINSURED PATIENTS

PAY NO MORE THAN $25† on each LOTEMAX® GEL prescription. Discounted pricing is also available for eligible uninsured patients. *

BE SURE TO ACTIVATE YOUR COUPON
Call 1-800-670-4615 or visit www.lotemaxgelpartdcoupon.com

†Offer varies at cash-only pharmacies. Please visit www.bauschaccessprogram.com for eligibility criteria and terms and conditions.

ELIGIBLE MEDICARE PART D PATIENTS

PAY NO MORE THAN $60† on each LOTEMAX® GEL prescription.

1 BE SURE TO ACTIVATE YOUR COUPON
Call 1-800-670-4615 or visit www.lotemaxgelpartdcoupon.com

2 BE SURE TO MAIL YOUR LETTER
Once you have redeemed your prescription at the pharmacy, be sure to mail in the prewritten letter (which was provided with your coupon) to your health plan. Health care plan address can be found on your Medicare provider card.

†Offer varies at cash-only pharmacies. Please visit www.lotemaxgelpartdcoupon.com for eligibility criteria and terms and conditions.

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LOTEMAX®
loteprednol etabonate
ophthalmic gel 0.5%

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LOTEMAX® (loteprednol etabonate ophthalmic gel) 0.5% safely and effectively. See full prescribing information for LOTEMAX®.

LOTEMAX® (loteprednol etabonate ophthalmic gel) 0.5%
Initial U.S. Approval: 1998

INDICATIONS AND USAGE
LOTEMAX is a corticosteroid indicated for the treatment of postoperative inflammation and pain following ocular surgery. (1)

DOSAGE FORMS AND STRENGTHS
LOTEMAX contains 5 mg/g of loteprednol etabonate, as a sterile preserved ophthalmic gel. (3)

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. (4)

WARNINGS AND PRECAUTIONS
• Intracocular 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. (5.1)

ADVERSE REACTIONS
The most common adverse drug reactions were anterior chamber inflammation (5%), eye pain (2%), and foreign body sensation (2%). (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.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 08/2016

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

5.6 Fungal Infections
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.

5.7 Contact Lens Wear
Patients should not wear contact lenses during their course of therapy with LOTEMAX.

6 ADVERSE REACTIONS
Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with infrequent optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, delayed wound healing and secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

The most common adverse drug reactions reported were anterior chamber inflammation (5%), eye pain (2%), and foreign body sensation (2%).

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 (35 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 (6 times the maximum daily clinical dose). Oral treatment of rats during organogenesis resulted in teratogenicity (absent innominate artery at ≥5 mg/kg/day doses, and cleft palate and umbilical hernia at ≥50 mg/kg/day) and embryotoxicity (increased post-implantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossification with ≥50 mg/kg/day). Treatment of rats with 0.5 mg/kg/day (6 times the maximum clinical dose) during organogenesis did not result in any reproductive toxicity. Loteprednol etabonate was maternally toxic (significantly reduced body weight gain during treatment) when administered to pregnant rats during organogenesis at doses of ≥5 mg/kg/day.

Oral exposure of female rats to 50 mg/kg/day of loteprednol etabonate from the start of the fetal period through the end of lactation, a maternally toxic treatment regimen (significantly decreased body weight gain), gave rise to decreased growth and survival, and retarded development in the offspring during lactation; the NOEL regimen (significantly decreased body weight gain during treatment) when administered to pregnant rats during organogenesis did not result in reproductive toxicity. Loteprednol etabonate was maternally toxic (increased body weight gain) when administered to pregnant rats during organogenesis at doses of ≥5 mg/kg/day.

There are no adequate and well controlled studies in pregnant women. LOTEMAX® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers
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.

8.4 Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use
No overall differences in safety and effectiveness have been observed between elderly and younger patients.

11 DESCRIPTION
LOTEMAX® (loteprednol etabonate ophthalmic gel) 0.5% contains a sterile, topical corticosteroid for ophthalmic use. Loteprednol etabonate is a white to off-white powder. Loteprednol etabonate is represented by the following structural formula:

\[
\text{Chemical Name:} \quad \text{chloromethyl 17α-[(ethoxycarbonyl)oxy]-11β-hydroxy-3-oxoandrosta-1,4-diene-17β-carboxylate}
\]

Each gram contains:
ACTIVE: Loteprednol Etabonate 5 mg (0.5%);
INACTIVES: Boric acid, edetate disodium dihydrate, glycerin, propylene glycol, sodium chloride, tyloxapol, water for injection, and sodium hydroxide to adjust to a pH of between 6 and 7.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the edema, fibrin deposition, capillary dilatation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. While glucocorticoids are known to bind to and activate the glucocorticoid receptor, the molecular mechanisms involved in glucocorticoid/glucocorticoid receptor-dependent modulation of inflammation are not clearly established. However, corticosteroids are thought to inhibit prostaglandin production through several independent mechanisms.

12.3 Pharmacokinetics
Loteprednol is lipid soluble and can penetrate 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 the inactive carboxylic acid metabolites, FJ-91 and FJ-90. The systemic exposure to loteprednol etabonate following ocular administration of LOTEMAX has not been studied in humans.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, 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 vivo in the Ames test, the mouse lymphoma tk assay, or in a chromosome aberration test in human lymphocytes, or in vivo in the single dose mouse micronucleus assay. Treatment of male and female rats with up to 50 mg/kg/day and 25 mg/kg/day of loteprednol etabonate, respectively, (600 and 300 times the maximum clinical dose, respectively) prior to and during mating did not impair fertility in either gender.

14 CLINICAL STUDIES
In two randomized, multicenter, double-masked, parallel-group, vehicle-controlled studies in 813 subjects with, post-operative inflammation, LOTEMAX was more effective compared to its vehicle in resolving anterior chamber inflammation and pain following cataract surgery. Primary endpoints were complete resolution of anterior chamber cells (cell count of 0) and no pain at post-operative day 8.

In these studies, LOTEMAX had a statistically significant higher incidence of subjects with complete clearing of anterior chamber cells (31% vs. 14-16%) and were pain free at post-operative day 8 (73-76% vs. 42-46%).

16 HOW SUPPLIED/STORAGE AND HANDLING
LOTEMAX® (loteprednol etabonate ophthalmic gel) 0.5% is a sterile ophthalmic gel supplied in a white low density polyethylene plastic bottle with a white controlled drop tip an and a pink polypropylene cap in the following size: 5 g in a 10 mL bottle (NDC 24208-503-07)
Use only if imprinted neckband is intact.
Storage: Store upright at 15º-25º C (59º-77º F).

17 PATIENT COUNSELING INFORMATION

17.1 Administration
Invert closed bottle and shake once to fill tip before instilling drops.

17.2 Risk of Contamination
Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the gel.

17.3 Contact Lens Wear
Patients should be advised not to wear contact lenses when using LOTEMAX.

17.4 Risk of Secondary Infection
If pain develops, redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician.

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