LOTEMAX is a corticosteroid indicated for the treatment of postoperative inflammatory pain following ocular surgery (1).

2 DOSAGE AND ADMINISTRATION

Apply one to two drops of LOTEMAX into the conjunctival sac of the affected eye four times daily beginning the day after surgery and continuing throughout the first 2 weeks of the postoperative period (2).

5 WARNINGS AND PRECAUTIONS

5.1 Intraocular Pressure (IOP) Increase

Prolonged use of corticosteroids may result in posterior subcapsular cataract formation.

8.1 Pregnancy

There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etabonate in pregnant women. There are no adequate and well-controlled studies with loteprednol etab0
17 Exposure to loteprednol etabonate following ocular administration of LOTEMAX has not been studied in humans. Loteprednol etabonate undergoes extensive metabolism to the inactive carboxylic acid metabolites, PJ-91 and PJ-90. The systemic prednisolone-related compounds so that it will undergo a predictable transformation to an inactive metabolite. Based upon in vivo preclinical metabolism studies, loteprednol etabonate is a corticosteroid. Its chemical name is chloromethyl 17α-hydroxy-3-oxoandrosta-1,4-diene-17β-carbonate. Its molecular formula is C_{26}H_{35}ClO_{6} and its chemical structure is:

\[
\text{C}_{26} \text{H}_{35} \text{ClO}_{6} \]

Each gram contains:
- ACTIVE: loteprednol etabonate 5 mg (0.5%)
- INACTIVES: basic acid, sodium diiuron dibutyrate, glycerol, polyvinylpyrrolidone, sodium chloride, tyloxapol, water for injection, and sodium hydroxide to adjust to a pH of between 6 and 7

PRECAUTIONS: benzalkonium chloride 0.001%

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Loteprednol etabonate is a corticosteroid. In vitro and in vivo preclinical metabolism studies, loteprednol etabonate undergoes extensive metabolism to the inactive carboxylic acid metabolites, PJ-91 and PJ-90.

12.2 Pharmacokinetics
Loteprednol etabonate 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 evidence from in vitro and in vivo preclinical metabolism studies, loteprednol etabonate undergoes extensive metabolism to the inactive carboxylic acid metabolites, PJ-91 and PJ-90. The systemic exposure to loteprednol etabonate following subcutaneous administration of LOTEMAX has not been studied in humans.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Loteprednol etabonate was not genotoxic in vitro in the Ames test, the mouse lymphoma tk assay, or in a chromosome aberration test in human lymphocytes, or in vivo in the mouse micronucleus test. Treatment of female and male rats with doses ≥ 25 mg/kg/day of loteprednol etabonate (12.5 mg/kg/day the RHOD based on body surface area, assuming 100% absorption) prior to and during mating caused decreased pregnancy and reduced the number of live fetuses/live births. The NOAEL for teratology in rats was 5 mg/kg/day (10 times the RHOD).

14 CLINICAL STUDIES

14.1 Pediatric Use
There are no data on the use of loteprednol etabonate in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for LOTEMAX and any potential adverse effects on the breastfed infant from LOTEMAX.

14.2 Lactation
Advise patients not to wear contact lenses when using LOTEMAX.

15 ADVERSE REACTIONS
5 g in a 10 mL bottle (NDC 24208-503-07)

17 PATIENT COUNSELING INFORMATION
Advise patients not to allow the dropper tip to touch any surface, as this may contaminate the gel.

18 HOW SUPPLIED/STORAGE AND HANDLING
Lotemax is a trademark of Bausch & Lomb Incorporated or its affiliates.

19 Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA
Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC