

## Lotemax® SM (loteprednol etabonate) – New Drug Approval

- On February 25, 2019, [Bausch and Lomb announced](#) the FDA approval of [Lotemax SM \(loteprednol etabonate\)](#) 0.38% ophthalmic gel, for the treatment of postoperative inflammation and pain following ocular surgery.
- Loteprednol etabonate is also available for ophthalmic use as the branded products [Alrex® 0.2% suspension](#), [Inveltys™ 1% suspension](#), [Lotemax 0.5% suspension](#), [Lotemax 0.5% gel](#), and [Lotemax 0.5% ointment](#).
  - Alrex is indicated for the temporary relief of the signs and symptoms of seasonal allergic conjunctivitis.
  - Inveltys, Lotemax gel and Lotemax ointment carry the same indication as Lotemax SM.
  - Lotemax suspension is indicated for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation, and for the treatment of postoperative inflammation following ocular surgery.
- Lotemax SM uses SubMicron (SM) technology to adhere to the ocular surface and then penetrate key ocular tissues.
- The approval of Lotemax SM was based on two vehicle-controlled studies in 742 patients who underwent cataract extraction with intraocular lens implantation. Lotemax SM was administered three times daily to the affected eye beginning the day after cataract surgery. The rates of patients receiving Lotemax SM who achieved complete clearing of anterior chamber cells and who were pain free at post-operative day 8 were compared to vehicle.
  - In study 1, the proportion of patients with complete clearing of anterior chamber cells and proportion of patients with complete resolution of pain at post-operative day 8 were 29% for Lotemax SM vs. 9% for vehicle (difference: 19; 95% CI: 11, 27) and 73% for Lotemax SM vs. 48% for vehicle (difference: 25; 95% CI: 15, 35), respectively.
  - In study 2, the proportion of patients with complete clearing of anterior chamber cells and proportion of patients with complete resolution of pain at post-operative day 8 were 31% for Lotemax SM vs. 20% for vehicle (difference: 10; 95% CI: 2, 19) and 76% for Lotemax SM vs. 50% for vehicle (difference: 26; 95% CI: 17, 35), respectively.
- Lotemax SM 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.
- Additional warnings and precautions of Lotemax SM include intraocular pressure increase, cataracts, delayed healing, bacterial infections, viral infections, fungal infections, and contact lens wear.
- There were no treatment-emergent adverse drug reactions that occurred in > 1% of patients in the three times daily group vs. vehicle.
- The recommended dose of Lotemax SM is one drop into the conjunctival sac of the affected eye three times daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period.

- Bausch and Lomb plans to launch Lotemax SM in April 2019. Lotemax SM will be available as a 0.38% sterile preserved ophthalmic gel.



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