Lotemax® (loteprednol etabonate) – Expanded indication

- On July 20, 2018, the FDA announced the approval of Bausch and Lomb's Lotemax (loteprednol etabonate) ophthalmic gel 0.5%, for the treatment of post-operative inflammation and pain following ocular surgery.
    - The expanded indication allows for pediatric use of Lotemax.
    - Previously, Lotemax was approved only in adult patients for the same indication.
- Lotemax 0.5% is also available as an ophthalmic suspension and an ointment.
    - Lotemax suspension is indicated for certain steroid-responsive inflammatory conditions when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.
    - Lotemax ointment carries the same indication as Lotemax gel, but is only indicated in adults.
- Loteprednol is also available as a branded ophthalmic 0.2% suspension (Alrex®) and a branded combination suspension (Zylet® [loteprednol 0.5%/tobramycin 0.3%]).
    - Alrex is indicated for the temporary relief of the signs and symptoms of seasonal allergic conjunctivitis.
    - Zylet is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.
- The expanded indication for Lotemax was based on a safety and efficacy study of 107 patients from birth to < 11 years of age undergoing cataract surgery. Patients were randomized to receive either Lotemax or prednisolone acetate ophthalmic suspension 1% four times daily for 14 days.
    - At day 14, the percentage of patients with complete clearing of anterior chamber inflammation was 57% in the Lotemax group vs. 63% in the prednisolone group.
    - In addition, pediatric use of Lotemax is also supported by evidence from adequate and well-controlled trials of Lotemax in adults.
- The recommended dosage of Lotemax for all patients is one to two drops 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 post-operative period.