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Lotemax (loteprednol etabonate ophthalmic suspension) 0.5%

Lotemax 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, and selected infective conjunctivides, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

Lotemax is less effective than prednisolone acetate 1% in two 28-day controlled clinical studies in acute anterior uveitis, where 72% of patients treated with Lotemax experienced resolution of anterior chamber cells, compared to 87% of patients treated with prednisolone acetate 1%. The incidence of patients with clinically significant increases in IOP (>10 mm Hg) was 1% with Lotemax and 6% with prednisolone acetate 1%. Lotemax should not be used in patients who require a more potent corticosteroid for this indication.

Lotemax is also indicated for the treatment of post-operative inflammation following ocular surgery.

IMPORTANT SAFETY INFORMATION

- Lotemax 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. Lotemax is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.
- Prolonged use of Lotemax is associated with several warnings and precautions, including glaucoma with optic nerve
 damage, defects in visual acuity and fields of vision, cataract formation, secondary ocular infections, occurrence of
 perforations in those with diseases causing corneal and scleral thinning, exacerbation or prolongation of viral ocular
 infections (including herpes simplex), delay in wound healing and increase in bleb formation following cataract surgery.
- If this product is used for 10 days or longer, intraocular pressure should be monitored. The initial prescription and renewal
 of the medication order beyond 14 days should be made by a physician only after examination of the patient with the aid of
 magnification. Fungal infections of the cornea may develop with prolonged use of corticosteroids.
- Ocular adverse reactions occurring in 5%-15% of patients treated with loteprednol etabonate ophthalmic suspension (0.2% - 0.5%) in clinical studies included abnormal vision/blurring, burning on instillation, chemosis, discharge, dry eyes, epiphora, foreign body sensation, itching, injection and photophobia.

 Please click here (/Portals/77/-/m/BL/United States/Files/Package Inserts/Pharma/lotemax-package-insert.pdf?ver=2016-09-26-093713-477)
 (354.4 KB, PDF) to view the Lotemax full Prescribing Information.

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Learn More

Please see <u>Prescribing</u> Information. (/Portals/77/-/m/BL/United States/Files/Package Inserts/Pharma/lotemaxpackage-insert.pdf?ver=2016-09-26-093910-470) (153 KB)

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