



LOTEMAX[®] ...

PROVEN
POWER

FOR THE
OCULAR SURFACE

- LOTE[®] 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, giant papillary conjunctivitis and seasonal allergic conjunctivitis⁸

Please see Important Risk Information about LOTE[®] on back cover.

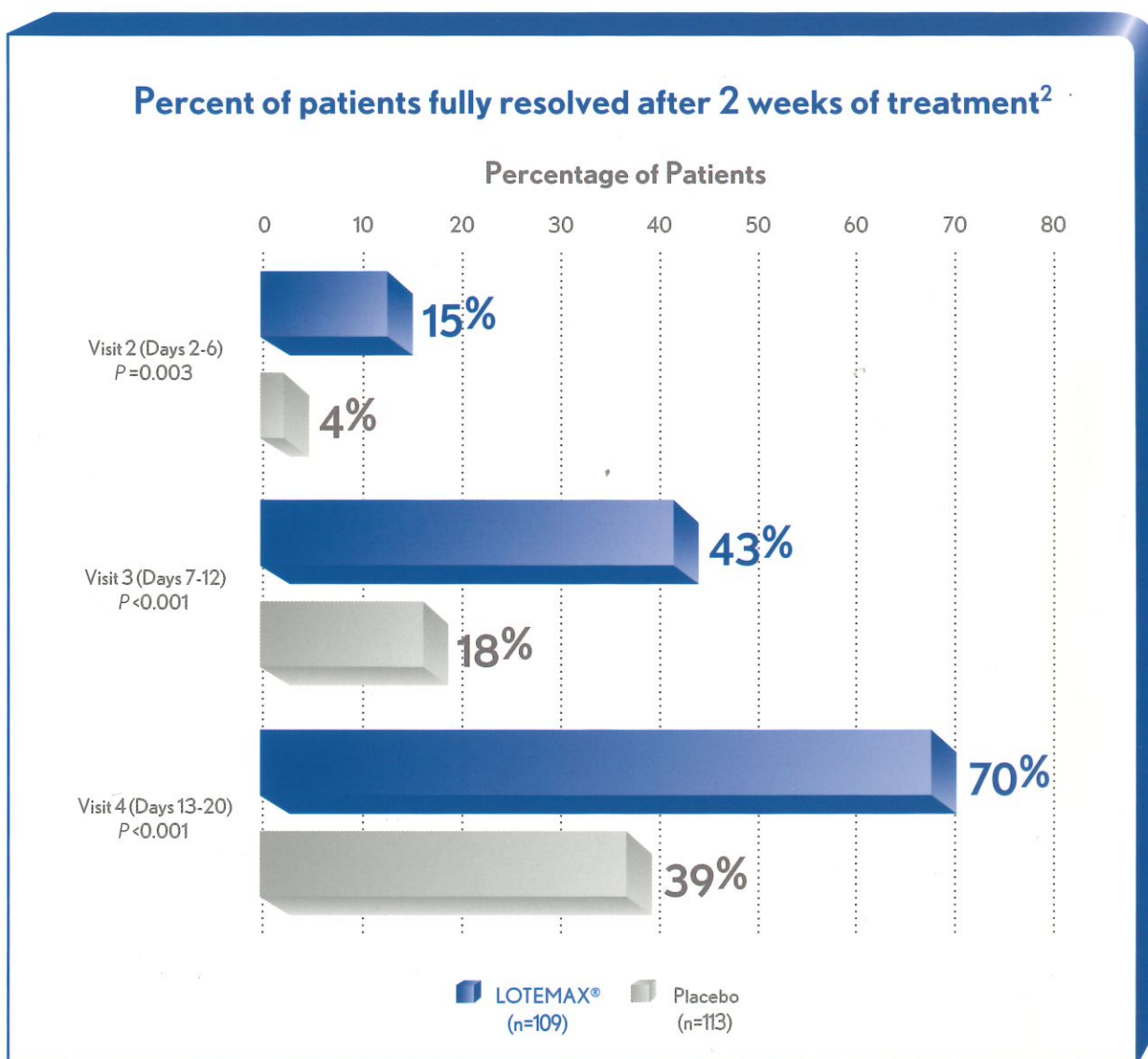
BAUSCH + LOMB

Lotemax[®]

loteprednol etabonate
ophthalmic suspension 0.5%

LOTEMAX[®]: POWERFUL EFFICACY IN POST-OPERATIVE INFLAMMATION²

LOTEMAX[®] fully resolved post-operative inflammation in these majority of patients²



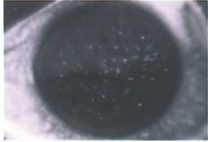
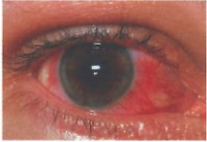
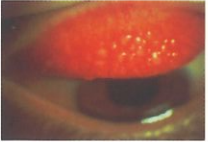
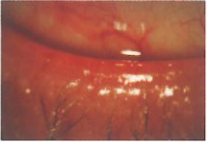
























ACI, anterior chamber inflammation; IOL, intraocular lens.

Study design: Randomized, double-masked, placebo-controlled, parallel-group, multicenter study demonstrated the efficacy and safety of LOTEMAX[®] in patients having cataract surgery with posterior chamber IOL implantation. Patients who exhibited a minimum ACI score (sum of cell and flare reaction) of at least 3 (0-9 scale) on the day after cataract removal with posterior chamber IOL implantation were included in the study. Treatment with LOTEMAX[®] was administered 4 times daily for up to 14 days after surgery.²

The primary endpoint was the resolution of ACI.²

LOTEMAX[®] IS INDICATED FOR A BROAD RANGE OF OCULAR SURFACE CONDITIONS²

LOTEMAX[®] treats these ocular surface conditions²:

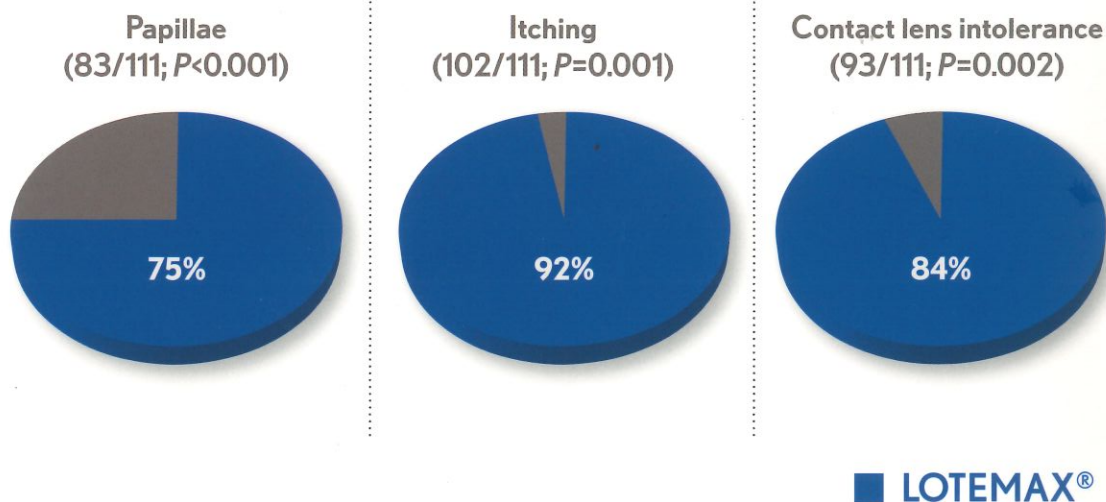
SYMPTOMS	CONDITIONS			
	Superficial punctate keratitis (SPK)	Episcleritis*	Giant papillary conjunctivitis (GPC)	Ocular rosacea
				
Light Sensitivity				
Irritation				
Impaired Vision				
Corneal Lesions				
Redness				
Tearing				
Mucus Discharge				
Itching				
Eyelid Swelling				

*Anterior segment of the globe.

LOTEMAX[®] DELIVERS PROVEN EFFICACY IN OCULAR SURFACE CONDITIONS⁵

Effectively treats a range of ocular inflammatory conditions, including GPC

Percentage of LOTE[®] patients with ≥ 1 grade improvement in the primary signs and symptoms of giant papillary conjunctivitis (GPC)^{5,†}



Study design: A prospective, double-masked, randomized, parallel-group, multicenter study comparing LOTE[®] with placebo in the treatment of GPC (N=220). The primary efficacy endpoint was defined as the proportion of patients showing a 1 grade improvement from baseline at their last visit in the severity of papillae, itching, and contact lens intolerance scores. Papillae had to be either grade 2 or 3 on a 0 to 3 grade scale, and the eye had to be red and inflamed. Itching was required to be at least 2 on a 0 to 4 grade scale and contact lens intolerance had to be at least 2 on a 0 to 3 grade scale.⁵

[†]P values derived from a comparison of the response rates of LOTE[®] and placebo in the treatment of the signs and symptoms of GPC.

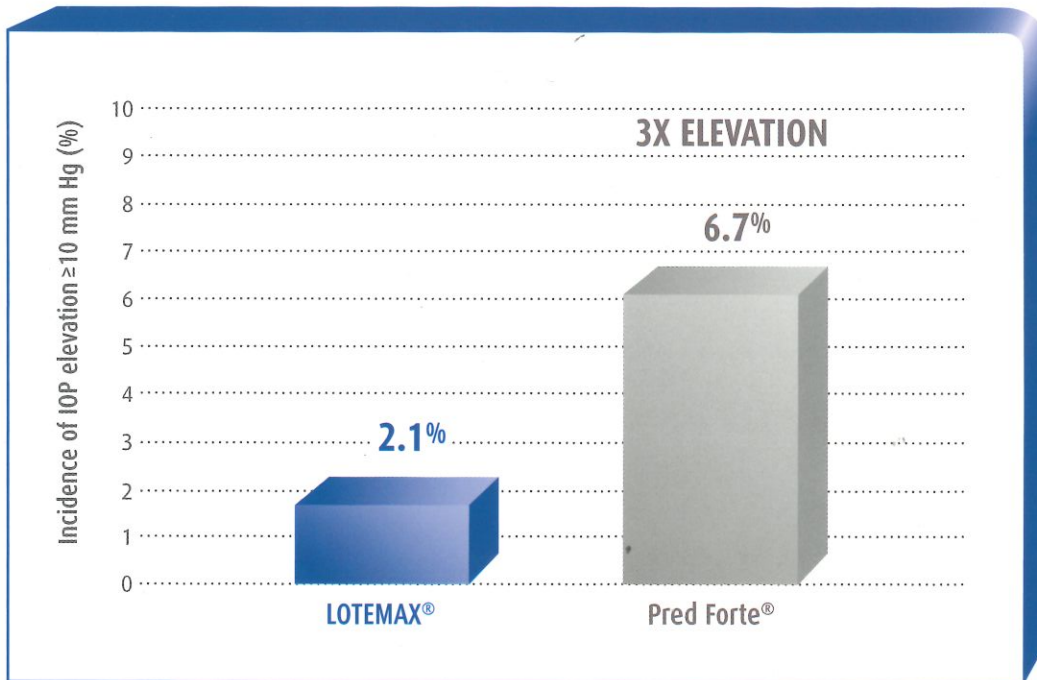
LOTE[®] demonstrated statistically significant improvements in bulbar and palpebral conjunctival injection⁵

Efficacy of LOTE[®] was observed by the end of the first week⁵

Lotemax.
loteprednol etabonate
ophthalmic suspension 0.5%

LOTEMAX[®]: SIGNIFICANTLY LESS IOP ELEVATIONS VERSUS PRED FORTE[®]

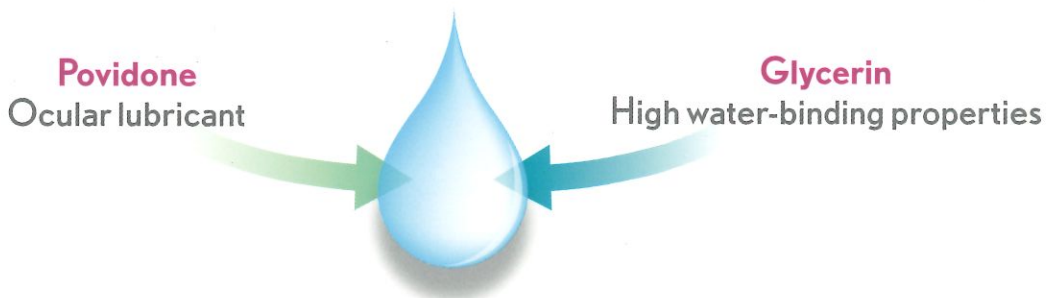
Pred Forte[®] was 3 times more likely to cause significant IOP elevation versus LOTE[®]



In a summation of controlled, randomized studies of individuals treated for 28 days or longer with LOTE[®], the incidence of significant elevation of IOP $\times 10$ mm Hg was 2.1% (14/664) among patients receiving LOTE[®] and 6.7% (11/164) among patients receiving Pred Forte[®]. Of the 14 patients in the LOTE[®] group with IOP elevations $\times 10$ mm Hg, 11 instilled medication while wearing contact lenses.^{3,5}

LOTE[®] offers a unique formulation

The only ocular steroid that contains the moisturizing ingredients povidone and glycerin⁵⁻⁷



LOTEMAX[®]: PROVEN POWER FOR THE OCULAR SURFACE

Indicated for a broad range of ocular surface conditions²

Unique formulation designed for the ocular surface

Proven efficacy in ocular surface conditions, including GPC⁵

3x less risk of IOP elevations vs Pred Forte^{6,7}



Important Risk Information about LOTE[®]

- 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, infection, infection, and photophobia

Please see additional Important Risk Information about LOTE[®] on Approved Malaysia PI.

References: 1. IMS NPA Quarterly Data 2011. 2. LOTE[®] Prescribing Information, April 2006. 3. Ophthalmic drug products for over-the-counter human use. Fed Regist. 2010;21(5):289. To be codified at 21 CFR §349. 4. Bartlett JD, Holland EJ, Usner DW, Paterno MR, Comstock TL. Tolerability of loteprednol/tobramycin versus dexamethasone/tobramycin in healthy volunteers: results of a 4-week, randomized, double-masked, parallel-group study. *Curr Med Res Opin.* 2008;24(8):2219-2227. 5. Asbell P, Howes J. A double-masked, placebo-controlled evaluation of the efficacy and safety of loteprednol etabonate in the treatment of giant papillary conjunctivitis. *CLAO J.* 1997;23(1):31-36. 6. Data on file, Bausch + Lomb Incorporated. 7. Novack GD, Howes J, Crockett RS, Sherwood MB. Change in intraocular pressure during long-term use of loteprednol etabonate. *J Glaucoma.* 1998;7(4):266-269. 8. Malaysia approved package insert

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Orbit Medica Sdn Bhd (921655-X)
No. 71, Jalan TPK 2/8, Taman Perindustrian Kinrara,
Sek2, 47180 Puchong, Selangor.
Tel: +603 8079 0005 / 1700 81 5005 Fax: +603 8079 0007

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