EyeKare

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For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

LOTEFORT™ LS LOTEPREDNOL ETABONATE OPHTHALMIC SUSPENSION 0.2% W/V

DOSAGE FORM : Ophthalmic Suspension

COMPOSITION :

Loteprednol Etabonate 0.2% w/v, Benzalkonium chloride Solution IP (as Preservative) 0.01% v/v, Water for Injections IP q.s.

CLINICAL PHARMACOLOGY : Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen and scar formation associated with inflammation. There is no generally accepted explanation for the mechanism of action of ocular corticosteroids. However, corticosteroids are thought to act by the induction of phospholipase A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2. Corticosteroids are capable of producing a rise in intraocular pressure (IOP).

Loteprednol etabonate is structurally similar to other corticosteroids. However, the number 20 position ketone group is absent. It is highly lipid soluble which enhances its penetration 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 *in vivo* and *in vitro* preclinical metabolism studies, loteprednol etabonate undergoes extensive metabolism to inactive carboxylic acid metabolites.

INDICATIONS AND USAGE : LOTEFORT LS 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 conjunctivitides, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

LOTEFORT LS is less effective than prednisolone acetate 1% in 28-day controlled clinical studies in acute anterior uveitis, where 72% of patients treated with LOTEFORT LS 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 mmHg) was 1% with LOTEFORT LS and 6% with prednisolone acetate 1%. LOTEFORT LS should not be used in patients who require a more potent corticosteroid for this indication.

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

WARNINGS AND PRECAUTIONS : Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Steroids should be used with caution in the presence of glaucoma.

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution.

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

For external use only. 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, such as slit lamp biomicroscopy and where appropriate, fluorescein staining.

If signs and symptoms fail to improve after two days, the patient should be re-evaluated.

If this product is used for 10 days or longer, intraocular pressure should be monitored even though it may be difficult in children and uncooperative patients (see WARNINGS).

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.

ADVERSE REACTIONS : Reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex and perforation of the globe where there is thinning of the cornea or sclera.

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. Other ocular adverse reactions occurring in less than 5% of patients include conjunctivitis, corneal abnormalities, eyelid erythema, keratoconjunctivitis, ocular irritation/pain/discomfort, papillae and uveitis. Some of these events were similar to the underlying ocular disease being studied.

Non-ocular adverse reactions occurred in less than 15% of patients. These include headache, rhinitis and pharyngitis.

In a summation of controlled, randomized studies of individuals treated for 28 days or longer with loteprednol etabonate, the incidence of significant elevation of intraocular pressure (≥10 mmHg) was 2% (15/901) among patients receiving loteprednol etabonate, 7% (11/164) among patients receiving 1% prednisolone acetate and 0.5% (3/583) among patients receiving placebo.

DOSAGE AND ADMINISTRATION : SHAKE WELL BEFORE USE.

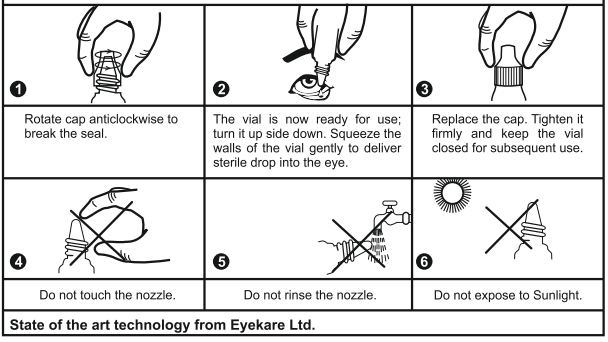
Steroid Responsive Disease Treatment: Apply one to two drops of LOTEFORT LS into the conjunctival sac of the affected eye four times daily. During the initial treatment within the first week, the dosing may be increased, up to 1 drop every hour, if necessary. Care should be taken not to discontinue therapy prematurely. If signs and symptoms fail to improve after two days, the patient should be re-evaluated (see **PRECAUTIONS**).

Post-Operative Inflammation: Apply one to two drops of LOTEFORT LS into the conjunctival sac of the operated eye four times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the post-operative period.

PACKING : Lotefort LS Ophthalmic Suspension is available in 5ml in ***Iyondellbasel Purell*** low density polyethylene dispensing system consisting of plastic bottle with good flexibility. Tamper evidence ring around the closure and neck area of the bottle.

STORAGE INSTRUCTIONS : Store in cool & dry place. Protect from light. Keep out of reach of children.
Use the solution within one month after opening the container.
For external use only.

INSTRUCTIONS FOR USE



State of the art technology from Eyekare Ltd.

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