Loteprednol Etabonate Ophthalmic Suspension 0.5%  

**DESCRIPTION:**
Loteprednol etabonate ophthalmic suspension contains a sterile, topical anti-inflammatory corticosteroid for ophthalmic use. Loteprednol etabonate is a white to off-white powder.

**INDICATIONS AND USAGE:**
Loteprednol etabonate ophthalmic suspension is indicated for the treatment of anterior chamber inflammation as measured by cell and flare. Placebo-controlled clinical studies demonstrated that loteprednol etabonate ophthalmic suspension was effective in reducing the signs and symptoms of allergic conjunctivitis during peak periods of pruritus.

**CONTRAINDICATIONS:**
Loteprednol etabonate ophthalmic suspension is contraindicated in patients with a known history of hypersensitivity to any of the ingredients of this preparation and to other corticosteroids. Loteprednol etabonate is also contraindicated in patients who require a more potent corticosteroid for this indication.

**WARNINGS:**
Prolonged use of corticosteroids may result in placental and fetal damage to the brain, retina, and in posterior subcapsular cataract formation. Steroids should be used with caution in patients with glaucoma.

**ADVERSE REACTIONS:**
Loteprednol etabonate ophthalmic suspension is associated with occasional side effects which are similar to those associated with other corticosteroids. These side effects include: transient worsening of pre-existing ocular hypertension, ocular hypotension, cataracts, and glaucoma.

**PRECAUTIONS:**
For ophthalmic use only. The initial prescription and renewal of the medication should be confined to 14 days, or until the signs and symptoms are controlled.

**PREGNANCY:**
Loteprednol etabonate ophthalmic suspension is a Component in Loteprednol Etabonate and Prednisolone Ophthalmic Suspension. Each mL of Loteprednol Etabonate ophthalmic suspension contains Loteprednol Etabonate 3.5 mg (0.5%), Prednisolone 0.1 mg, and Sodium Hydroxide may be added to adjust the pH to 5.0–6.0. The suspension is essentially isotonic with a tonicity of 300–440 mOsm/L.

**CLINICAL PHARMACOLOGY:**
Loteprednol etabonate is a synthetic corticosteroid which is structurally similar to other corticosteroids. It is used as a topical anti-inflammatory agent in the treatment of various eye conditions.

**PHARMACOKINETICS:**
Loteprednol etabonate is absorbed systemically following ocular administration.

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Loteprednol etabonate is absorbed systemically following ocular administration.
Information for Patients: Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the suspension. If you develop a rash, tenderness, itching or inflammation, immediately stop using Loteprednol etabonate ophthalmic suspension and contact your physician. As with all topical preparations containing benzalkonium chloride, patients should be advised not to wear soft contact lenses while using Loteprednol etabonate ophthalmic suspension.

Contraindications: Hypersensitivity to Loteprednol etabonate or to any of the excipients contained in Loteprednol etabonate ophthalmic suspension has not been reported in the literature. Loteprednol etabonate ophthalmic suspension should not be used in the eyes of patients with active or latent herpes simplex keratitis, except when treating iritis associated with herpes zoster keratitis.

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Loteprednol etabonate ophthalmic suspension has not been shown to cause enlarge abnormalities when administered to pregnant monkeys at doses up to 50 mg/kg/day. Loteprednol etabonate had no effect on the duration of gestation or parturition when administered orally to rabbits at doses up to 50 mg/kg/day. Loteprednol etabonate had no effect on the duration of gestation or parturition when administered orally to rabbits at doses up to 50 mg/kg/day. Loteprednol etabonate was shown to cause enlargement abnormalities in the rat embryo when administered orally at doses up to 10 mg/kg/day. Loteprednol etabonate is not known to cause birth defects in humans. Therefore, Loteprednol etabonate should not be used during pregnancy unless in a life-threatening situation and the benefit outweighs the potential risk to the fetus.

Lactation: Loteprednol etabonate ophthalmic suspension should not be used by nursing mothers, as systemic absorption of the medication to the breastfed infant is not known. Loteprednol etabonate ophthalmic suspension should be used by nursing mothers only if the potential benefit justifies the potential risk to the infant.

ADVERSE REACTIONS: Adverse reactions associated with ophthalmic solutions include a localized erythema, edema, lid reactions, chemosis, papillary hyperemia, tearing, discomfort, and ocular surface irritation. Systemic adverse reactions have not been reported with the use of this ophthalmic suspension.

Non-ocular adverse reactions occurring in less than 15% of patients include headache, rhinitis and pharyngitis. Non-ocular adverse reactions occurring in less than 5% of patients include conjunctivitis, corneal abnormalities, eyelid erythema, epiphora, foreign body sensation, itching, injection, and photophobia. Other ocular adverse reactions occurring in 5% to 15% of patients treated with Loteprednol etabonate ophthalmic suspension include ocular surface infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with sources of systemic corticosteroids, and cataract formation.

INFORMATION FOR PATIENTS: Patients should be advised not to wear soft contact lenses while using Loteprednol etabonate ophthalmic suspension. If pain develops, redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician. As with all topical preparations containing benzalkonium chloride, patients should be advised not to wear soft contact lenses while using Loteprednol etabonate ophthalmic suspension. Patients should be advised not to touch the suspension directly with hands or other instruments. Patients should be advised to consult a physician if the eye is injured or if there are other unusual eye conditions.

DOSAGE AND ADMINISTRATION: See package insert for dosage and administration instructions.

HOW SUPPLIED: Loteprednol etabonate ophthalmic suspension is supplied in a white opaque LDPE plastic dropper bottle with LDPE white opaque dropper and LDPE white dropper cap as follows:

5 mL: (NDC 072756-233-00) 10 mL: (NDC 072756-233-02) 15 mL: (NDC 072756-233-04)

Storage: Store tightly closed between 20°-25°C (68°-77°F), DO NOT FREEZE.

KEEP OUT OF REACH OF CHILDREN.

Revised

Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512

Manufactured by: Sun Pharmaceutical Industries Ltd. Turbhe, Navi Mumbai, Maharashtra, India.

Halol-389350, Gujarat, India.

Baska Ujeti Road, Ujeti, Surat, Gujarat, India.