PACKAGE INSERT

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

ALREX Ophthalmic Suspension

COMPOSITION

Each mℓ contains:

Loteprednol etabonate 2,00 mg (0,2 % *w/v*)

Benzalkonium chloride (preservative) 0,10 mg (0,01 % *w/v*)

The other inactive ingredients are edetate disodium dihydrate, glycerine, povidone, purified water and tyloxapol.

PHARMACOLOGICAL CLASSIFICATION

A15.2 Ophthalmic preparations with corticosteroids

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Loteprednol etabonate is a corticosteroid with anti-inflammatory activity.

Cortienic acid is an inactive metabolite of hydrocortisone. Analogues of cortienic acid are also devoid of corticosteroid activity. Loteprednol etabonate is an ester derivative of one of these analogues, ΔP^1P cortienic acid etabonate (PJ-91).

Loteprednol etabonate is capable of producing a rise in intra-ocular pressure (IOP) in susceptible individuals. Intraocular pressure returned to normal on discontinuation of loteprednol.

Pharmacokinetic properties

Oral and ocular administration of loteprednol etabonate in normal volunteers have shown that there is low or undetectable plasma concentrations of either the unchanged material or the metabolite. Plasma cortisol concentrations were measured and no evidence of adrenal cortex suppression was observed.

INDICATIONS

ALREX is indicated for the short-term (6 weeks) symptomatic treatment of seasonal allergic conjunctivitis in adults.

CONTRAINDICATIONS

ALREX is contraindicated in:

- individuals with known hypersensitivity to loteprednol, other corticosteroids or to any other ingredients of ALREX
- viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella
- untreated purulent ocular infections
- eyes with suspected or confirmed infections
- amoebic infections
- mycobacterial infections
- fungal diseases of ocular structures
- glaucoma (see WARNINGS AND SPECIAL PRECAUTIONS)
- children under the age of 18 years

- pregnancy and lactation (see PREGNANCY AND LACTATION)

Paediatric use:

Safety and effectiveness in paediatric patients have not been established.

WARNINGS AND SPECIAL PRECAUTIONS

As the possibility of adverse effects on the corneal permeability, and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations, cannot be excluded, regular ophthalmological examination is required.

Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

Do not wear soft contact lenses when using ALREX.

Prolonged use of ALREX may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. ALREX should not be used in the presence of glaucoma (see CONTRAINDICATIONS).

Prolonged use of ALREX may suppress the host response and thus increase the possibility 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, ALREX may mask the infection or enhance existfng infection (see CONTRAINDICATIONS).

If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated. If this product is used for 10 days or longer, intraocular pressure should be monitored.

This product is sterile when packaged. Do not allow the dropper tip to touch any surface, as this may contaminate the suspension.

ALREX should be discarded 28 days after opening.

Effects on Ability to Drive and use Machines

Use of ALREX may cause abnormal or blurred vision. Patients should not drive or operate machinery until their vision is clear.

INTERACTIONS

Since loteprednol etabonate is barely detected in plasma levels following the topical administration of ALREX, it is not expected to affect the pharmacokinetics of systemically administered medicines.

The potential of ALREX eye suspension to increase the intraocular pressure may be adversely affected by systemically administered medicines with anticholinergic activity. In patients receiving concomitant ocular hypotensive therapy, the addition of ALREX may increase intra-ocular pressure and decrease the apparent ocular hypotensive effect of these medications. Concurrent administration of cycloplegics may increase the risk of raised intra-ocular pressure.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

PREGNANCY AND LACTATION

Pregnancy:

Safety in pregnancy has not been established, and it should therefore not be used during this period.

Lactation:

Mothers using ALREX should not breastfeed their babies. There is insufficient data to support the safe use of ALREX eye drops in lactating women. Therefore such use is contra-indicated.

DOSAGE AND DIRECTIONS FOR USE

SHAKE VIGOROUSLY BEFORE USING.

Apply one to two drops into the conjunctival sac of the affected eye(s) four times daily. During the initial treatment within the first week, the dosing may be increased up to one drop every hour, if necessary.

If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated. If this product is used for 10 days or longer, intraocular pressure should be monitored.

Treatment should not exceed six weeks.

If more than one topical ophthalmic product is being used, the medicinal products should be administered at least 10 minutes apart.

SIDE EFFECTS

The following adverse events were reported as related to the treatment with loteprednol etabonate (0,005 % - 0,5 %) during clinical trials:

Common (≥1/100, <1/10)

Vision disorders: Increased intraocular pressure, itchy eyes, conjunctival hyperaemia, epiphora,

burning/stinging, foreign body sensation, abnormal vision, eye discharge, dry eyes, photophobia, eye discomfort, chemosis and blurred vision.

Body as a whole – general disorders: Headache

Uncommon (≥1/1 000, <1/100)

Vision disorders: Eyelid erythema, eye pain, anterior chamber cells, eyelid abnormality, iritis, uveitis, corneal abnormality, eye irritation, ciliary flush, keratitis, anterior chamber flare, keratic precipitate, macular oedema, papilla, conjunctival oedema, eye disorder, fluorescein staining, hyphema, anterior chamber inflammation, ophthalmitis, sticky eye, anterior chamber synechia.

Skin and appendages disorders: Rash, urticaria

Central & peripheral nervous system disorders: Nervousness

Special senses other, disorders: Taste disturbances

Gastro-intestinal disorders: Diarrhoea, nausea, vomiting

Cardiovascular disorders, general: Migraine

Respiratory system disorders: Rhinitis, pharyngitis, increased cough

Urinary system disorders: Urinary tract infection

Body as a whole – general disorders: Asthenia, chest pain, chills, facial oedema, fever, pain

The following additional adverse events were spontaneously reported as related to the use of ALREX:

Vision disorders: Conjunctivitis, glaucoma, lacrimation discharge, mydriasis, vitreous disorder, corneal lesion, cataract, abnormal accommodation, corneal opacity, corneal ulcer, visual field defect, vitreous discharge

Skin and appendages disorders: Herpes simplex, sweating, pruritus, skin discolouration

Musculoskeletal system disorders: Spasms

Central & peripheral nervous system disorders: Dizziness, paraesthesia, tremor, anxiety, insomnia

Special senses other, disorders: Otitis media, parosmia, discharge from the ear, ear pain

Psychiatric disorders: Depression

Gastro-intestinal disorders: Dyspepsia

Metabolic and nutritional disorders: Glycosuria

Cardiovascular disorders, general: Palpitations, vasodilation, hypertension, tachycardia

Respiratory system disorders: Lung disorder, voice alteration, laryngismus, asthma, dyspnoea, laryngitis, lung discharge

Body as a whole – general disorders: Allergic reaction, aggravated reaction, abnormalities of the hair, feeling abnormal, anorexia, malaise, photosensitivity

Reactions associated with ophthalmic steroids such as ALREX include elevated intra-ocular pressure in steroid responsive patients, which may be associated with optic nerve damage, visual acuity and field defects, posterial 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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

No case of overdose has been reported. Acute over dosage is unlikely to occur via the ophthalmic route.

IDENTIFICATION

White to off-white milky suspension.

PRESENTATION

White plastic dropper bottle with a control drop tip containing 1mℓ, 2,5 mℓ, 5 mℓ or 10 mℓ of suspension. The labelled plastic bottle is packed together with a package insert into a printed unit carton.

STORAGE INSTRUCTIONS

Store upright. Store at or below 25 °C. Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

38/15.2/0203

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Soflens (Pty) Ltd

254 Hall Street

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0157

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