

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

# PREDEYE<sup>TM</sup>

# PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION USP 1% W/W

## COMPOSITION

Prednisolone Acetate IP 1% w/v, Benzalkonium Chloride Solution (as Preservative) IP 0.02% 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<sub>2</sub> 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<sub>2</sub>.

Corticosteroids are capable of producing a rise in intraocular pressure.

**INDICATIONS AND USAGE:** 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 conjunctivitis, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation; corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies.

**CONTRAINDICATIONS:** Prednisolone acetate ophthalmic suspension 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. Prednisolone acetate ophthalmic suspension is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

**WARNINGS : NOT FOR INJECTION. For external use only.** 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. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections.

Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.

Acute purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication. If this product is used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be checked frequently.

The use of steroids after cataract surgery may delay healing and increase the incidence of fibrous formation. 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; frequent slit lamp microscopy is recommended. Corticosteroids are not effective in mustard gas keratitis and Sjogren's keratoconjunctivitis.

**PRECAUTIONS:** General : The initial prescription and renewal of the medication order 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. As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate. If this product is used for 10 days or longer, intraocular pressure should be monitored (See Warnings) Prolonged application to the eye of preparation has caused raised intra-ocular pressure and reduced visual function.

**Information for Patients :** If inflammation or pain persists longer than 48 hours or becomes aggravated, the patient should be advised to discontinue use of the medication and consult a physician. This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the bottle tips to eyelids or to any other surface. The use of this bottle by more than one person may spread infection. Keep bottle tightly closed when not in use. Keep out of reach of children. Use the suspension within one month after opening the container.

**Carcinogenesis, Mutagenesis, Impairment of Fertility :** No studies have been conducted in animals or in humans to evaluate the potential of these effects.

**Pregnancy :** Teratogenic Effects, Pregnancy Category C : Prednisolone has been shown to be teratogenic in mice when given in doses 1-10 times the human dose. Dexamethasone, hydrocortisone and prednisolone were ocularly applied to both eyes of pregnant mice five times per day 10 through 13 of gestation. A significant increase in the incidence of cleft palate was observed in the fetuses of the treated mice. There are no adequate and well controlled studies in pregnant women. Prednisolone acetate ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing mothers :** It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from prednisolone acetate, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Paediatric Use:** Safety and effectiveness in paediatric patients have not been established.

**Geriatric Use:** No overall differences in safety and effectiveness have been observed between elderly and younger patients.

**ADVERSE REACTIONS :** Adverse reactions include, in decreasing order of frequency, elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation, and delayed wound healing. Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticism after use of topical steroids. Corticosteroid-containing preparations have been reported to cause acute anterior uveitis and perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperemia, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids. The development of secondary ocular infection (bacterial, fungal and viral) has occurred. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroid. The possibility of fungal invasion should be considered in any persistent corneal ulceration where steroid treatment has been used (See warnings).

**DOSAGE AND ADMINISTRATION :** SHAKE WELL BEFORE USE. Two drops topically in the eye(s) four times daily. In cases of bacterial infections, concomitant use of anti-infective agents is mandatory. 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). The dosing of prednisolone acetate ophthalmic suspension may be reduced, but care should be taken not to discontinue therapy prematurely. In chronic conditions, withdrawal of treatment should be carried out by gradually decreasing the frequency of applications.







**PACKING :** Predeye Eye Drops are available in 10ml in **lyondell/basel 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 below 25°C. 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		
 <b>1</b>	 <b>2</b>	 <b>3</b>
Rotate cap anticlockwise to break the seal.	The vial is now ready for use; turn it up side down. Squeeze the walls of the vial gently to deliver sterile drop into the eye.	Replace the cap. Tighten it firmly and keep the vial closed for subsequent use.
 <b>4</b>	 <b>5</b>	 <b>6</b>
Do not touch the nozzle.	Do not rinse the nozzle.	Do not expose to Sunlight.
<b>State of the art technology from Eyekare Ltd.</b>		

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EV067/R01