PRED®

Prednisolone Acetate USP
Sterile Ophthalmic Suspension

DESCRIPTION

PRED® is a preparation of Prednisolone Acetate ophthalmic suspension. Prednisolone is a glucocorticoid that, on the basis of weight, has 3 to 5 times the anti-inflammatory potency of hydrocortisone. Glucocorticoids inhibit the edema, fibrin deposition, capillary dilation and phagocytic migration of the acute inflammatory response, as well as capillary proliferation, deposition of collagen, and scar formation. Prednisolone is thought to act by the induction of phospholipase A2 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 release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

INDICATIONS

For the treatment of steroid-responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.

DOSAGE AND ADMINISTRATION

Shake well before using. Instill one drop into the conjunctival sac two to four times daily. During the initial 24 to 48 hours, the dosing frequency may be increased if necessary. Care should be taken not to discontinue therapy prematurely.

CONTRAINDICATIONS

PRED® 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, fungal infections of ocular structures and tuberculosis of the eye. Also contraindicated in individuals with known or suspected hypersensitivity to Prednisolone Acetate of this preparation and to other corticosteroids.

SIDE EFFECTS

Adverse reactions include, in decreasing order of frequency, elevation of intraocular pressure, posterior subcapsular cataract formation, eye penetration (scleral or corneal perforation), and delayed wound healing. 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 in some cases.

PRECAUTION AND WARNING

Prolonged use of corticosteroids may suppress the host immune response and thus increase the hazard of secondary ocular infections. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated. As fungal infections of the cornea are particularly prone to develop with long-term corticosteroid applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used. Fungal cultures should be taken when appropriate. If this product is used for 10 days or longer, intraocular pressure should be monitored.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. This preparation should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when **PRED**® is administered to a nursing woman.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light & wet place. Keep out of reach of children. Store in an upright position. To prevent contamination of the dropper tip and suspension, care should be taken. Don't touch the eyelids, surrounding areas, finger or other surfaces with the dropper tip of the bottle. The bottle should be tightly closed when not in use. Do not use after 4 weeks of first opening.

PACKAGING

PRED® Ophthalmic Suspension: Plastic dropper bottle containing 5 mL sterile ophthalmic suspension. Each mL contains Prednisolone Acetate USP 10 mg.

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Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
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R/PM1728 V01