Predflam

Prednisolone Acetate
Sterile Ophthalmic Suspension

Presentation

Predflam: Each ml sterile ophthalmic suspension contains Prednisolone Acetate USP 10 mg.
Preservative: Benzalkonium Chloride 0.01%.

Pharmacological Action

Prednisolone Acetate is a corticosteroid that, on the basis of weight, has 3 to 5 times the anti-inflammatory potency of Hydrocortisone. Corticosteroids inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, and fibroblast proliferation, deposition of collagen and scar formation associated with inflammation.
Prednisolone Acetate is 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 release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.

Indications

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, edema and inflammation. Also indicated in the treatment of corneal injury from chemical, radiation, thermal burns or penetration of foreign bodies.

Dosage and Application

Shake well before use.
Instill 1 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

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.
It is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation.

Side Effects

Adverse reactions include, elevation of intraocular pressure (IOP) with possible development of glaucoma, infrequent optic nerve damage, posterior subcapsular cataract formation and delayed wound healing.
Corticosteroid-containing preparations have also 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.

Precautions

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 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. If this product is used for 10 days or longer, intraocular pressure should be monitored.

Drug Interactions

Specific drug interaction studies have not been conducted with Prednisolone Acetate USP 1% ophthalmic suspension.

Use in Pregnancy and Lactation

There are no adequate and well controlled studies in pregnant women. Prednisolone Acetate USP 1% ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. So this drug should be used nursing mother if the potential benefit justifies the potential risk to the fetus.

Overdose

Overdose will not ordinarily cause acute problems. If accidentally ingested, drink fluids to dilute.

Storage

Store in a cool (below 30°C) and dry place away from light. Keep out of the reach of children. Do not touch the dropper tip to surfaces since this may contaminate the suspension. After one month of the opening do not use the medicine of dropper.

Packing

Predflam: Each plastic dropper bottle containing 5 ml sterile ophthalmic suspension.

Manufactured by :
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