

PrDEXAMETHASONE

Dexamethasone Sodium Phosphate Ophthalmic Solution USP, 0.1%
Dexamethasone Phosphate Equivalent

CORTICOSTEROID

DESCRIPTION AND ACTIONS

Dexamethasone is a fluorinated synthetic corticosteroid with anti-inflammatory activity. Although the precise mechanism of action is not known, corticosteroids inhibit edema, fibrin deposition, capillary dilatation, and migration of leukocytes and phagocytes in the acute inflammatory response. They also reduce capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation.

Following instillation into the eye Dexamethasone is absorbed into the aqueous humour and systemic absorption occurs. However, because of the low dose, clinical evidence of absorption is not observed.

NON-MEDICINAL INGREDIENT

Benzalkonium Chloride 0.01% w/v as preservative, Monobasic Sodium Phosphate, Dibasic Sodium Phosphate, Sodium Chloride, Disodium Edetate, Sodium Thiosulfate and water for injection.

INDICATIONS

EYE: Steroid responsive, non-infectious inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis (do not use in epithelial herpes simplex 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 injuries, such as aseptic thermal, radiation or chemical burns, and corneal injuries from penetration of foreign bodies or after surgery.

EAR: Dexamethasone may also be used in steroid responsive inflammatory conditions of the auditory meatus, such as allergic otitis externa, seborrheic dermatitis, eczema and selected purulent and nonpurulent infective otitis externa when the hazard of steroid use is accepted to obtain an advisable reduction in edema and inflammation. Dexamethasone should not be used if the ear drum is perforated.

CONTRAINDICATIONS

Dexamethasone should not be used in acute superficial herpes simplex keratitis, fungal diseases of ocular or auricular structures, in infectious tuberculosis lesions of the eye or ear, acute infectious stage of vaccinia and other viral disease of the cornea and conjunctiva, when the ear drum is perforated or if the patient has a known sensitivity to corticosteroids or any ingredient of Dexamethasone.

WARNINGS

The safety of intensive or prolonged use of topical steroids in pregnancy has not been established and therefore use should be avoided during pregnancy, unless the potential benefits outweigh the possible risks.

PRECAUTIONS

Following the uncomplicated removal of foreign bodies, corticosteroid use is generally not indicated.

Use in the treatment of stromal herpes simplex requires great caution; frequent slit-lamp examination is required. In patients on long term use, frequent corneal and lens examination is advisable. Cataract and corneal melting have been reported with prolonged use of some topical steroids.

Discontinue Dexamethasone if any signs of sensitivity are observed.

Dexamethasone may mask, activate or enhance infection. If the possibility of infection is present, the use of concomitant anti-infective therapy should be considered. If the infection does not respond quickly, discontinue Dexamethasone therapy until the infection is controlled by other treatment.

With prolonged steroid use, fungal infections may develop. This should be considered if a persistent corneal ulceration occurs with steroid use.

Increased intraocular pressure can occur with extended steroid use of 1-2 weeks or longer. Use with caution in patients known to have glaucoma using tonometric monitoring.

Patients should be advised to avoid contamination of the applicator tip during use.

ADVERSE EFFECTS

Systemic reactions may occur with extended topical use of corticosteroids. The appearance of ocular herpes simplex in patients taking systemic adrenocortical steroids orally or locally in the eye for other conditions has been known to have occurred with topical use of corticosteroids. In diseases causing thinning of the cornea or sclera, perforation has been reported to occur with topical steroid use. Reactions occurring most often from the presence of an anti-infective component of allergic sensitization. The reactions due to the corticosteroid component in decreasing order of frequency are: elevation of 10P with possible development of glaucoma, and infrequent optic nerve damage; posterior sub-capsular cataract formation; and delayed wound healing. Rarely, filtering blebs have been reported with topical steroids used following cataract surgery. Stinging or burning may occasionally occur.

DOSAGE AND ADMINISTRATION

The duration of treatment will vary with the type of lesion may extend from a few days to several weeks according to therapeutic response. Relapses, more common in chronic active lesions than self-limited conditions, usually respond to retreatment.

EYE: Instill 1 or 2 drops Dexamethasone into the conjunctival sac every hour during the day and every 2 hours during the night as initial therapy. When a favourable response is observed, reduce dosage to 1 drop every 4 hours. Later, further reduction in dosage to 1 drop 3 or 4 times daily may control symptoms.

EAR: Clean the aural canal and dry. Instill Dexamethasone directly into the aural canal with a dropper. A suggested initial dosage is 3 to 4 drops 2 or 3 times daily. Once a favourable response is obtained dosage may be gradually reduced and eventually discontinued. The ear may be packed with a gauze wick saturated with Dexamethasone Solution.

Keep the wick moist with the solution and remove from the ear after 12 to 24 hours. Treatment may be repeated as often as necessary at the discretion of the physician.

STORAGE: Store between 15°C to 30°C. Protect from light.

SUPPLIED: Dexamethasone is provided in a 5ml plastic squeeze bottle with an applicator tip.

DIN 02023865

pharma STULLN

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