Inflavis®

Dexamethasone Phosphate
Eye/Ear Drops

Description

Dexamethasone Phosphate has been demonstrated by animal and human studies based on oral application to possess approximately six to seven times the potency of prednisolone and at least 30 times the potency of cortisone. The potency of the compound is accomplished by the addition of a methyl radical and a fluorine atom to the prednisolone radical. Dexamethasone is absorbed rapidly after oral administration with a half-life of about 190 minutes. Sufficient absorption may occur after topical application to the skin and eye to produce systemic effects.

Indications

Eye: Dexamethasone Phosphate is indicated for treatment of steroid responsive inflammatory conditions of the conjunctiva, cornea and anterior segment of the eye such as: anterior uveitis, iritis, cyclitis, allergic and vernal conjunctivitis, herpes zoster keratitis, superficial punctate keratitis and non-specific superficial keratitis.

Also indicated for the treatment of corneal injury from chemical, radiation or thermal burns or following penetration by foreign bodies. Indicated for post-operative use to reduce inflammatory reactions and suppress graft reaction.

Ear: Indicated in the steroid responsive inflammatory conditions of the external auditory meatus, such as allergic otitis externa, selected purulent and non-purulent infective otitis externa.

Dosage and Administration

Eye: The frequency of instillation of drops and the duration of treatment will vary depending upon the severity of the underlying condition and the response to treatment.

Severe inflammations require one to two drops instilled into the eye every thirty to sixty minutes until a satisfactory response occurs.

Subconjunctival or systemic steroid therapy should be considered if there is no response. When a favourable response has been observed reduce the dosage towards one drop every four hours.

Ear: Instill two or three drops to the ear at two or three hour interval. The frequency of dosage and duration of the treatment may vary with the type of lesion and severity.

Contraindications

Herpes simplex and other viral diseases of the cornea and conjunctiva, fungal disease, ocular tuberculosis, untreated purulent infections and hypersensitivity to any component of the preparation. Patients with soft contact lenses should not use this preparation.

Adverse Effects

Topical steroid use may result in increased intraocular pressure leading to optic nerve damage, reduced visual acuity and visual field defects.

Intensive or prolonged use of topical corticosteroids may lead to the formation of posterior subcapsular cataracts. In those diseases causing thinning of the cornea or sclera, perforation of the globe may occur. Viral and fungal infections may be exacerbated by steroids. Transient stinging or burning may occur on instillation of the drops. Systemic side effects may occur with extensive use.

Precautions

Topical corticosteroids should never be given for an undiagnosed red eye as inappropriate use is potentially blinding. Because of the risk of "steroid glaucoma" and cataract formation the intraocular pressure and the lens must be checked frequently during use of this preparation. To avoid the risk of enhancement of herpetic corneal disease, frequent slit-lamp examination is essential. Topical steroids may mask or enhance the activity of acute purulent eye infections. In such cases antibiotic therapy is mandatory. Persistent corneal ulceration following long-term topical steroid use may be due to fungal invasion.

Topical corticosteroids are not effective in mustard gas keratitis or Sjogren's keratoconjunctivitis.

High risk group

Pregnancy & Lactation:

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human pregnancy.

Drug Interactions

None relevant to topical use.

Overdose

Long-term intensive topical use may lead to systemic effects. Oral ingestion of the contents of the bottle (up to 10 mls) is unlikely to lead to any serious adverse effects.

Pharmaceutical Precautions

Store in a cool and dry place, away from light. Keep out of reach of children.

Commercial Pack

Inflavis® Eye/Ear Drops: Plastic dropper bottle contains 5 ml sterile eye drops. Each ml contains Dexamethasone Sodium Phosphate USP equivalent to Dexamethasone Phosphate 1 mg.

BEXIMCO PHARMA

Manufactured by

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