

Gludex

Dexamethasone Sodium Phosphate BP
Sterile Eye/Ear Drops

Composition:

Each ml contains Dexamethasone Sodium Phosphate BP 1 mg.

Indications:

Eye: Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe, such as allergic conjunctivitis, keratitis, iritis, scleritis, corneal injury from chemical or thermal burns, or penetration of foreign bodies.

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 & Administration:

Eye: Instill one or two Gludex drops into the conjunctival sac every hour during the day and every two hours during the night as initial therapy. When a favorable response is observed, reduce dosage to one drop every four hours. Later, further reduction in dosage to one drop three or four times daily may suffice to control symptoms.

Ear: Instill two or three Gludex 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:

Patients wearing contact lenses, herpes simplex & other viral conditions, mycosis, glaucoma, newborn babies, fungal diseases of ocular or auricular structures, hypersensitivity to any glucocorticoids or corticoids.

Side-effects:

A slight burning sensation may occur for a short time after instilling the drops into the eye. After several weeks of administration to predisposed patients, there may be a reversible increase in intraocular pressure. Regular ocular pressure checks are advisable. Systemic adverse reactions may also occur after long-term topical application of corticosteroids in children. Others include cataract and corneal softening.

Precautions & Warnings:

- If no improvement is observed after 7-8 days, other therapeutic measures should be considered.
- Corticosteroids may mask, activate or exacerbate ocular infections.
- Due to the risk of systemic response, the administration to the children under 2 years of age and to hyper or hypotonic patients are not advisable.
- During treatment, the intra-ocular pressure should be measured regularly.
- Prolonged use may result intraocular hypertension and/or glaucoma, with damage to the optic nerves defects in visual acuity and fields of vision, and posterior sub-capsular cataract formation.
- Patients wearing contact lenses must not use the drops during the time the lenses are worn.

Use in Pregnancy and lactation:

It is drugs of pregnancy Category-C. It should only be administered during pregnancy if the potential benefit exceeds the probable risk to the fetus. It should be given to lactating mother if prescribed by the physician.

Drug Interaction:

None relevant to topical use.

Storage:

- Store at a temperature of 15-25°C, in a dry place and away from light.
- Close the dropper immediately after use.
- Do not use for longer than one month after first opening.
- Keep out of the reach of the children.
- It is advisable to destroy any remaining medicament after completing the treatment.

How Supplied:

Plastic dropper bottle containing 5 ml sterile eye/ear drops.

Manufactured by :



KEMIKO PHARMACEUTICALS LTD.

Bangladesh