

Celudex Sterile Eye & Ear Drops

Dexamethasone USP 0.1%

Composition : Each ml of Celudex drops contains: Dexamethasone USP 1.00 mg.

Pharmacology : Corticosteroid binds to the glucocorticoid receptor, inhibiting pro-inflammatory signals, and promoting anti-inflammatory signals. Patients taking corticosteroids should be counseled regarding the risk of hypothalamic - pituitary-adrenal axis suppression and increased susceptibility to infections.

Indications : Eye : Non-infectious forms of conjunctivitis, keratitis and blepharitis, especially of allergic origin. Inflammation of the anterior uvea (iritis, iridocyclitis), scleritis, episcleritis, orbital myositis and sympathetic ophthalmia. **Ear :** Redness, itching and swelling caused by certain ear problems.

Dosage and administration: Eye: Administer 1 drop 3-5 times daily into the conjunctival sac. **Acute cases :** up to 1 drop hourly. **Ear :** 3 or 4 drops in the ear two or three times a day. Or, as directed by the registered physician.

Contraindication : Hypersensitivity to the ingredients, injuries and ulcerous processes of the cornea, Herpes simplex and other viral infections, mycosis, glaucoma. Similarly, Celudex 0.1% should not be administered to newborn babies.

Precautions : If no improvement is observed after 7-8 days treatment, other therapeutic measures should be considered. Corticosteroids may mask, activate or exacerbate eye infections. Due to the risk of systemic response, the administration to children under 2, is not advisable. During treatment with Celudex 0.1% the intraocular pressure should be measured regularly. Patients wearing contact lenses must not use the eye drops during the time the lenses are worn.

Side effects : After several weeks administration to predisposed patients there may be a reversible increase in intraocular pressure. Systemic adverse reactions may occur after long-term topical application of corticosteroids (above all in children). Isolated cases of cataract and corneal softening have been reported after long-term treatment with steroids.

Pregnancy and lactation : Controlled studies have not been performed with pregnant women. Under these circumstances Dexamethasone 0.1% should only be administered if the potential benefit exceeds the foreseeable risk to the foetus.

Use in child : Safety and efficacy in infants below the age of 1 year have not been established.

Drug Interactions : None relevant to topical use.

Overdose : There is no data available.

Storage : Store below 30°C in a dry place. Keep out of reach of children.

Packing : Celudex eye and ear drops : 5 ml in plastic dropper bottle.

Manufactured by



DRUG INTERNATIONAL LTD.

Tongi, Gazipur, Bangladesh