

Dexagen C

Dexamethasone Phosphate & Chloramphenicol Sterile Eye Drops

Presentation

Dexagen C : Each ml sterile eye drops contains Dexamethasone Phosphate 1 mg (as Dexamethasone Sodium Phosphate USP) & Chloramphenicol BP 5 mg.

Preservative: Benzalkonium Chloride 0.01%

Vehicle: Polyethylene Glycol 400 8%

Pharmacological Action

Dexamethasone is a cortisone derivative with an anti-inflammatory action 30 times stronger than that of hydrocortisone. Like other glucocorticoids, it is anti-allergic, anti-exudative and anti-proliferative. As any anti-inflammatory glucocorticoid, one of the actions of Dexamethasone is to inhibit phospholipase A₂, the first step in prostaglandin synthesis. Also, Dexamethasone inhibits the chemotactic infiltration of neutrophils into the site of inflammation. In order to reduce the risk of spread of the anti-inflammatory process in case of infection, the action of Dexamethasone is supplemented antibioticly by Chloramphenicol. Chloramphenicol is a low molecular weight, predominantly lipophilic antibiotic and is effective against both Gram-positive and Gram-negative bacteria and also against spirochaete, salmonellas, rickettsiae and chlamydiae (trachoma). The mechanism of action has been shown to be by selective inhibition of bacterial protein synthesis.

Indications

Acute and chronic keratitis and conjunctivitis of an infectious, allergic but non-viral nature. Infections of the anterior uvea (iritis, iridocyclitis). Scleritis, episcleritis and myositis. Post-operative management of cataract, glaucoma, and strabismus.

Dosage and Application

Insert one drop into the conjunctival sac 3-5 times per day. Acute cases: up to 1 drop every hour.

Contraindications

Hypersensitivity to any ingredients of the product. Injuries and ulcerating conditions of the cornea, particularly those of viral origin (herpes simplex, vaccinia), purulent infections of the conjunctiva and eyelids, tuberculous infections, mycosis, glaucoma, severe blood disorders due to bone marrow depression and hepatic dysfunctions, new-born babies.

Side Effects

A slight sense of burning may occur for a short time after instillation. The patient may notice a bitter taste shortly after instillation. When used for several weeks, a reversible increase in eye pressure is possible in predisposed patients. Regular pressure checks are advisable.

Partially irreversible hematodyscrasia (aplastic anemia, pancytopenia, leuko-penia, thrombocytopenia, agranulocytosis) has been observed in isolated cases following topical use of Chloramphenicol. However, the severity and the moment of manifestation did not correlate with the dosage used in these studies.

Precautions

Corticosteroids may mask, activate or aggravate an infection in the eye. As with all corticosteroids, the dosage for babies and infants under 2 years of age should be selected with caution. If no improvement is seen after 7-8 days of treatment, other therapeutic measures should be considered.

Use in Pregnancy and Lactation

Animal experiments with Chloramphenicol have shown adverse effects on the fetus. However, no controlled human studies are available. Dexamethasone and Chloramphenicol should not be given to pregnant patients, to new-born infants or during lactation.

Over Dose

Overdose through local administration is unlikely. In case of accidental oral intake, specific measures to reduce resorption should be taken. There is no specific antidote.

Storage Conditions

Store between 2-8° C . Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. After one month of the opening do not use the medicine of dropper.

Commercial Pack

Dexagen C : Each plastic dropper bottle containing 5 ml sterile eye drops.

Manufactured by :



GENERAL
Pharmaceuticals Ltd.

Unit-2, Gazipur, Bangladesh

