

Dexagen

Dexamethasone Phosphate
Sterile Eye / Ear Drops & Eye Ointment

Presentation

Dexagen Drops: Each ml of eye / ear drop contains Dexamethasone Phosphate 1 mg (as Dexamethasone Sodium Phosphate USP).

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| <i>Preservative:</i> | Sodium | Perborate | 0.01%. |
| <i>Vehicle:</i> | Hydroxypropyl | Methylcellulose | 0.3% |

Dexagen Ointment: Each gm of sterile eye ointment contains Dexamethasone Phosphate 0.5 mg (as Dexamethasone Sodium Phosphate USP).

Pharmacological Action

The action of Dexamethasone is to inhibit the phospholipase A_2 , the first step in prostaglandin synthesis. Also, Dexamethasone inhibits the chemotactic infiltration of neutrophils into the site of inflammation. Its anti-inflammatory activity is 30 times greater and its overall therapeutic effectiveness 8-10 times greater than that of hydrocortisone. Like other glucocorticoids, it is anti-allergic, anti-exudative and anti-proliferative. Therapeutic concentrations of Dexamethasone are found in both the cornea and aqueous humor 15-30 minutes after local application of single drop of 0.1% solution. These concentrations persist for 4-6 hours.

Indications

Eye: Dexamethasone ophthalmic solution is indicated for the treatment of

- Allergic non-infectious blepharitis and conjunctivitis.
- Non-infectious keratitis, punctate keratitis, disciform keratitis.
- Inflammation of the anterior uvea (iritis, iridocyclitis).
- Scleritis, episcleritis and myositis.
- Post-operative management of cataract, strabismus & other ocular surgeries.

Ear: Dexamethasone is indicated for the treatment of inflammatory conditions of the external auditory meatus, such as allergic otitis externa, selected purulent and nonpurulent infective otitis externa.

| Dosage | and | Application |
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Dexagen Drops:

Eye:

Instill one or two drops of solution 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.

Ear:

Clean the aural canal thoroughly and sponge dry. Instill the solution directly into the aural canal. A suggested initial dosage is 3 or 4 drops two or three times a day. When a favorable response is obtained, reduce dosage gradually and eventually discontinue.

Dexagen Ointment: Apply small amount to the conjunctiva 3 to 4 times a day. Once improvement is observed, may gradually reduce frequency before discontinuation.

Contraindications

Injuries and ulcerating processes of the cornea, particularly those of bacterial or viral origin (herpes simplex, vaccinia), purulent infections of the conjunctiva and eyelids, tuberculosis, mycosis, glaucoma. Fungal diseases of ocular or auricular structures, Hypersensitivity to any component of this product, Perforation of a drum membrane.

Side Effects

In predisposed patients, application of corticosteroids for a period of several weeks may cause a reversible rise in intraocular pressure. Pressure measurements at regular intervals are therefore essential.

Precautions

Corticosteroids may mask, activate or aggravate an infection of the eye. If no improvement is seen after a few days application, other form of treatment should be used.

Drug Interactions

Specific drug interaction studies have not been conducted with Dexamethasone.

Use in Pregnancy and Lactation

Animal experiments with dexamethasone have shown adverse effect on the fetus. However, no control human studies are available. Dexamethasone ophthalmic preparation should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Over Dose

Overdose through local or accidental oral administration is not likely.

Storage Conditions

Store in a cool and dry place away from light. Keep out of reach of children. Do not touch the dropper tip or tip of the tube since this may contaminate the solution & ointment. After one month of the opening do not use the medicine of dropper or tube.

Commercial Pack

Dexagen Drops: Each plastic dropper bottle containing 5 ml sterile eye / ear drops.

Dexagen Ointment: Each tube containing 3 gm sterile eye ointment.