Cinarex®-D

Dexamethasone and Tobramycin

Eye Drops

Description

Dexamethasone is glucocorticoid. It has an anti-inflammatory and anti-allergic action. It is used topically in the treatment of inflammatory conditions of the anterior segment of the eye. The efficacy of corticosteroids for the treatment of inflammatory conditions of the eye is well established. Corticosteroids achieve their anti-inflammatory effects through suppression of vascular endothelial cell adhesion molecules, cyclooxygenase I or II, and cytokine expression. This action culminates in a reduced elaboration of pro-inflammatory mediators and the suppression of adhesion of circulation leukocytes to the vascular endothelium, thereby preventing their aggression into inflamed ocular tissue. Dexamethasone has marked anti-inflammatory activity with reduced mineralocorticoid activity compared with some other steroids, and is one of the most potent anti-inflammatory agents.

Endophthalmitis is most frequently caused by Gram-positive bacteria (80-90%) including staphylococci, Bacillus species and streptococci, while Gram-negative organisms account for 10 to 20 percent of cases. Tobramycin in the combination is included to provide antibacterial protection against susceptible bacteria. In vitro studies have shown tobramycin to be a broad spectrum antibiotic active against most common ocular pathogens, including methicillin-susceptible and methicillin-resistant staphylococci, some streptococci and most all Gram-negative species. Recent studies with tobramycin have shown the compound to be active (MIC < 8ug/ml) against recently isolated Gram-positive ocular isolates (68%), and against Gram-negative bacteria (98%).

Indications

Eye: This combination eye drops are indicated for reduction of inflammation and prophylaxis of infection following cataract surgery.

Dosage

Eye: Adults: One drop instilled into the conjunctival sac(s) every 4 to 6 hours while the patient is awake. During the initial 24 to 48 hours, the dosage may be increased to one drop every two hours while the patient is awake, for a maximum of 24 days. Frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely.

Use in the Elderly: Clinical studies have indicated dosage modifications are not required for use in the elderly.

Children: Safety and effectiveness in children have not been established.

Adverse Effects

Adverse reactions have occurred with steroid/anti-infective combination drugs, which can be attributed to the steroid component, the anti-infective component, or the combination. Exact incidence figures are not available. The most frequent adverse reactions to topical ocular tobramycin are hypersensitivity and localised ocular toxicity, including lid itching and swelling, and conjunctival erythema. These reactions occur in less than 4% of patients. If topical ocular tobramycin is administered concomitantly with systemic aminoglycoside antibiotics, care should be taken to monitor the total serum concentration. The reactions due to the steroid component are: elevation of intraocular pressure (IOP), with possible development of glaucoma, and infrequent optic nerve damage; posterior subcapsular cataract formation; and delayed wound healing.

Contraindication

Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella and other viral disease of the cornea and conjunctiva. Mycobacterial infections of the eye caused by, but not limited to, acid-fast bacilli such as Mycobacterium tuberculosis, Mycobacterium leprae, or Mycobacterium avium. Fungal diseases of ocular structures. Untreated purulent infection of the eye. Hypersensitivity to any component of the medication.

Precaution

Prolonged use may result in overgrowth of nonsusceptible organisms including fungi; in ocular hypertension and/or glaucoma, with damage to the optic nerve, 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.

High Risk Group

Pregnancy & Lactation: Safety for use during pregnancy and lactation in humans has not been established. No adequate and well-controlled studies in pregnant women have been conducted. Subcutaneous administration of tobramycin to pregnant animals has not revealed any teratogenic effects. There may be a risk of fetal ototoxicity if aminoglycoside antibiotics are administered during human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate and intra-uterine growth retardation. Therefore, a very small risk exists for such effects in human pregnancy. This eye drops should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Studies have not been conducted to determine if these drugs are secreted in human milk. Because many drugs are secreted in human milk, a decision should be taken to discontinue nursing while using this combination eye drops.

Drug Interactions

No specific interaction studies were performed with this combination eye drops.

In case of concomitant therapy with other topical ophthalmic medicines, an interval of 10 minutes should be allowed between successive applications.

Pharmaceutical Precautions

Store in a cool and dry place, away from light. Keep out of reach of children. Shake well before each use.

Commercial Pack

Cinarex®-D Eye Drops: Plastic dropper bottle contains 5 ml sterile suspension. Each ml contains Dexamethasone USP 1 mg and Tobramycin USP 3 mg.

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