Neofloxin®-D

Dexamethasone and Ciprofloxacin

Eye/Ear 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 potency of the compound is accomplished by the addition of a methyl radical and a fluorine atom to the prednisolone radical. Dexamethasone is absorbed rapidly after oral administration with a half-life of about 190 minutes. Sufficient absorption may occur after topical application to the skin and eye to produce systemic effects.

Ciprofloxacin has cidal and inhibitory activities against bacteria which result from an interference with DNA gyrase, an enzyme needed by the bacterium for the synthesis of DNA. Thus, vital information from the bacterial chromosomes cannot be transcribed, which causes a break-down of bacterial metabolism.

Ciprofloxacin has a very high in vitro activity against almost all gram negative microorganisms including Pseudomonas aeruginosa. It is also effective against gram positive bacteria, such as Staphylococci and Streptococci. Anaerobes are in general less susceptible.

Indications

Eye: This combination eye drop is indicated for the treatment of steroid responsive inflammatory ocular conditions where bacterial infections or risk of bacterial infections co-exist. The use of a combination drug with an anti-infective component is indicated where the risk of infection is high or where is an expectation that potentially dangerous numbers of bacteria will be present in the eye. The combination can also be used for post-operative inflammation and any other ocular inflammation associated with infection.

Ear: It is indicated for the treatment of ear infections accompanied by inflammation such as otitis externa, otitis media and chronic suppurative otitis media etc. The combination can also be used for post-operative inflammation of ear.

Dosage

Eye: One or two drops to be instilled into conjunctival sac(s) every four to six hours. During the initial 24 to 48 hours, the dosage may be increased to one to two drops every two hours. Frequency should be decreased gradually or warranted in clinical signs. Care should be taken not to discontinue therapy prematurely.

Ear: For all infections two to three drops every two to three hours initially. Frequency should be decreased gradually as warranted by improvement in clinical signs.

Side Effect

The most frequently reported drug-related adverse reactions seen with Ciprofloxacin are transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, conjunctivitis/keratitis, periocular/facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness, and eye pain. Rare reports of dizziness have been received.

The reactions due to the steroid component are elevation of intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve damage, posterior sub capsular cataract formation, and delayed wound healing.

Contraindication

Known hypersensitivity to any ingredient of the product. Herpes simplex and other viral conditions, mycosis, glaucoma, newborn babies, fungal diseases of ocular or auricular structures.

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: This combination should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in human milk. It is also not known whether Ciprofloxacin is excreted in human milk following topical ophthalmic administration. Because many drugs are excreted in human milk, caution should be exercised when the combination is administered to a nursing woman. Moreover, because of the potential of serious adverse reactions from Ciprofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug taking into account the importance of the drug to the mother.

Drug Interactions

Dexamethasone: None relevant to topical use.

Ciprofloxacin: Specific drug interaction studies have not been conducted with ophthalmic ciprofloxacin. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, to interfere with the metabolism of caffeine, and to enhance the effect of the oral anticoagulant, warfarin, and its derivatives. Transient elevation in serum creatinine has been reported in patients receiving cyclosporin concomitantly with systemic ciprofloxacin.

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

Neofloxin®-D Eye/Ear Drops: Plastic dropper bottle contains 5 ml sterile suspension. Each ml contains Dexamethasone USP 1 mg and Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin 3 mg.

BEXIMCO PHARMA

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