

Neomycin, Polymyxin, Dexamethasone Ophthalmic Solution

Description

Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Solution is a multiple dose anti-infective steroid combination in a sterile suspension for topical application.

Neomycin Sulfate is the sulfate salt of neomycin B and C which are produced by the growth of *Streptomyces fradiae* Waksman. It has a potency equivalent to not less than 600 micrograms of neomycin base per milligram, calculated on an anhydrous basis.

Polymyxin B Sulfate is the sulfate salt of Polymyxin B1 and B2 which are produced by the growth of *Bacillus polymyxa* Migula. It has a potency of not less than 6,000 Polymyxin B units per milligram, calculated on an anhydrous basis.

Indications and Usage

For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists.

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe where the inherent risk of steroid use in certain cases of infective conjunctivitis is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical radiation or thermal burns; or penetration of foreign bodies.

The use of a combination drug with an anti-infective component is indicated where the risk of infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

Dosage

Apply to 1-2 drops to eye(s) every 4 to 6 hours

Contraindications

Epithelial herpes simplex keratitis, vaccinia, varicella and many other viral diseases of the cornea and conjunctiva. Mycobacterial infection of the eye. Fungal diseases of ocular structures. Hypersensitivity to a component of the medication.

Pregnancy. Pregnancy C

Dexamethasone has been shown to be Teratogenic in mice and rabbits following topical ophthalmic application in multiples of the therapeutic dose.

In the mouse, corticosteroids produce fetal resorptions and a specific abnormality, cleft palate. In the rabbit, corticosteroids have produced fetal resorptions and multiple abnormalities involving the head, ears, limbs, palate, etc.

There are no adequate or well-controlled studies in pregnant women. Neomycin, Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

Adverse Reactions

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 since no denominator of treated patients is available.

Reactions occurring most often from the presence of the anti-infective ingredients are allergic sensitizations. The reactions due to the steroid component are; elevation of intraocular pressure with

possible development of glaucoma, and infrequent optic nerve damage; posterior sub capsular cataract formation; and delayed wound healing.

Secondary Infection

The development of secondary infection has occurred after use of combinations containing steroids and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids. The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used.

Secondary bacterial ocular infection following suppression of host responses also occurs.