Neo-Polycin® HC
neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone acetate
Ophthalmic Ointment USP
STERILE Rx Only

DESCRIPTION: Neomycin and polymyxin B sulfates, bacitracin zinc and hydrocortisone acetate ophthalmic ointment is a sterile antimicrobial and anti-inflammatory ointment for ophthalmic use. Each gram contains: neomycin base equivalent to 3.5 mg neomycin base, polymyxin B sulfate equivalent to 10,000 polymyxin B units, bacitracin zinc equivalent to 400 bacitracin units, hydrocortisone acetate 10 mg (1%), in a white petrolatum and mineral oil base.

Corticosteroids have been found to be teratogenic in rat and rabbit embryonic development. In rabbits, administration of corticosteroids during the period of organogenesis results in retardation of growth and production of distortions and structural defects in various organs including the central nervous system. These abnormalities may be detected in animals subjected to corticosteroid administration for periods as short as 7-10 days. Depending on the stage of embryonic development at the time of administration, these effects can result in fetal resorption, delayed fetal development, or visceromegaly. The concurrent administration of corticosteroids and antimicrobials may have advantages for patients who are unlikely to respond to the treatment regimens used alone. Consideration should be given to the role of corticosteroids in the management of ocular diseases which are potentially self-limiting in nature.

The anti-infective component in neomycin and polymyxin B sulfates, bacitracin zinc and hydrocortisone acetate ophthalmic ointment is included to provide action against specific organisms susceptible to it. Neomycin sulfate and polymyxin B sulfate are active in vitro against susceptible strains of the following microorganisms: Staphylococcus aureus, streptococci including Streptococcus pneumoniae, Escherichia coli, Haemophilus influenzae, Klebsiella/Enterobacter species, Neisseria species, and Pseudomonas aeruginosa. The product does not provide adequate coverage against Serratia marcescens (see INDICATIONS AND USAGE).

Indications and Usage: Neo-Polycin® HC Ophthalmic Ointment is indicated for steroid-responsive inflammatory ocular diseases. The product does not provide adequate coverage against Serratia marcescens (see INDICATIONS AND USAGE).

Contraindications: Neo-Polycin® HC Ophthalmic Ointment is contraindicated in most viral diseases of the cornea and conjunctiva including: epithelial herpes simplex keratitis (dendritic keratitis), vaccinia and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. Neomycin and polymyxin B sulfates, bacitracin zinc and hydrocortisone acetate ophthalmic ointment is also contraindicated in individuals who have shown hypersensitivity to any of its components. Hypersensitivity to the antibiotic component occurs at a higher rate than for other components.

Neo-Polycin® HC Ophthalmic Ointment is supplied in 3.5 g (1/8 oz) sterile tamper evident tube with ophthalmic tip.

WARNINGS: NOT FOR INJECTION INTO THE EYE. Neomycin and polymyxin B sulfates, bacitracin zinc and hydrocortisone acetate ophthalmic ointment should not be introduced into the anterior chamber of the eye. Ophthalmic ointments may retard corneal wound healing. Prolonged use of corticosteroids may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Prolonged use may suppress the host immune response and thus increase the risk of secondary ocular infections. Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation. Acute purulent infections of the eye may be masked or enhanced by the presence of corticosteroid medication. If these products are used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in cooperative patients. Corticosteroids should be used with caution in the presence of glaucoma.

Intracocular pressure should be checked frequently. The use of corticosteroids after cataract surgery may delay healing and increase the risk of papillary edema. Use of the ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of corticosteroid medication in the treatment of herpes simplex requires great caution. Failure to be aware of this can result in severe local irritation. Topical antibiotics, particularly neomycin sulfate, may cause cutaneous sensitization. A precise incidence of hypersensitivity reactions (primarily skin rash) due to topical antibiotics is not known. The manifestations of sensitization to topical antibiotics are usually itching, reddening, and edema of the conjunctiva and eyelid. A sensitization reaction may manifest simply as a failure to heal. During long-term use of topical antibiotic products, periodic examination for such signs is advisable, and the patient should be told to discontinue the product if they are observed. Symptoms usually subside quickly on withdrawing the medication. Applications of products containing these ingredients should be avoided for the patient thereafter (see PRECAUTIONS).

PRECAUTIONS: General: The initial prescription and renewal of the medication order beyond 8 grams should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining. If signs and symptoms fail to improve after two days, the patient should be re-evaluated. As fungal infections of the cornea are particularly prone to develop coincidentally with long-term corticosteroid applications, fungal infection should be suspected in any patient who develops a corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken, if appropriate. If this product is used for 10 days or longer, intraocular pressure should be monitored (see WARNINGS). There have been reports of bacterial keratitis associated with the use of topical ophthalmic products in multiple-dose containers which have inadvertently been contaminated by patients, most of whom had a concurrent corneal disease or a disruption of the ocular epithelial surface (see PRECAUTIONS).

Information for Patients: If administration of this product is expected to cause delayed wound healing, patients should be advised to discontinue the use of the medication and consult a physician. This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the tip of the tube to eyelids or any other surface. The use of this tube by more than one person may spread infection. Keep out of the reach of children.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals to evaluate carcinogenic potential have not been performed with polymyxin B sulfate or bacitracin. Treatment of cultured human lymphocytes in vitro with neomycin increased the frequency of chromosome aberrations at the highest concentrations (80 μg/mL) tested; however, the effects of neomycin on carcinogenesis and mutagenesis in humans are unknown. Neonatal rats, rabbits, and mice were administered bacitracin in the diet at doses up to 100 gm/ton of diet. Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids. Studies to determine mutagenicity with hydrocortisone acetate have revealed negative results. Polymyxin B has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown. No adverse effects on male or female fertility, litter size, or survival were observed in rabbits given bacitracin zinc 100 gm/ton of diet. Long-term animal studies have not been performed to evaluate the effect on fertility of topical corticosteroids.

Pregnancy: Teratogenic Effects: Pregnancy Category C. In humans, bacitracin zinc and polymyxin B sulfates, bacitracin zinc and hydrocortisone acetate ophthalmic ointment, 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.

Pediatric Use: Safety and effectiveness in children have not been established. Geriatric Use: No overall differences in safety or effectiveness have been observed in between elderly and younger patients. Adverse Reactions: Adverse reactions have occurred with corticosteroid/anti-infective combination drugs which can be attributed to the corticosteroid component, the anti-infective component, or the combination. The exact incidence is not known. Reactions occurring most often with the corticosteroid component are allergic sensitization reactions including itching, swelling, and conjunctival erythema (see WARNINGS). More serious hypersensitivity reactions, including anaphylaxis, have been reported rarely. The reactions due to the corticosteroid component in decreasing order of frequency are: elevation of intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve damage; posterior subcapsular cataract formation; and delayed wound healing. Secondary Infection: The development of the secondary ocular infection has occurred after use of combinations containing corticosteroids and antimicrobials. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of a corticosteroid. The possibility of fungal invasion must be considered in any persistent corneal ulceration where corticosteroid treatment has been used (see WARNINGS). Local irritation on installation has been reported. If signs and symptoms fail to improve after two days, the patient should be re-evaluated (see PRECAUTIONS).

DOSAGE AND ADMINISTRATION: Apply the ointment in the affected eye every 3 to 4 hours, depending on the severity of the condition. Not more than 8 grams should be prescribed initially and the prescription should not be refilled without further evaluation as outlined in PRECAUTIONS above. HOW SUPPLIED: Neo-Polycin® HC Ophthalmic Ointment is supplied in 3.5 g (1/8 oz) sterile tamper evident tube with ophthalmic tip.

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