Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension, USP
Sterile
Rx only
DESCRIPTION
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension, USP is a multiple dose anti-inflammatory steroid combination in a sterile suspension form for topical application. The chemical structure for the active ingredient, dexamethasone, is:

Established name: dexamethasone

Chemical name: pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-,(11β,16α)-.

The other active ingredients are neomycin sulfate and polymyxin B sulfate. The structural formula for neomycin sulfate is:

Established name: neomycin

Chemical name: neomycin sulfate, C23H46N6O13, xH2SO4

Molecular weight: 615 (base)

Each mL contains: Actives: neomycin sulfate equivalent to neomycin 3.5 mg, polymyxin B sulfate 10,000 units, dexamethasone 0.1%. Inactives: hypromellose 2910 0.5%, sodium chloride, polysorbate 20, hydrochloric acid and/or sodium hydroxide (to adjust pH), purified water, benzalkonium chloride 0.004% (preservative).

CLINICAL PHARMACOLOGY
Corticosteroids suppress the inflammatory response to a variety of agents and they probably delay or slow healing. Since corticosteroids may inhibit the body’s defense mechanism against infection, a concomitant antimicrobial drug may be used when this inhibition is considered to be clinically significant in a particular case.

When a decision to administer both a corticosteroid and an antimicrobial is made, the administration of such drugs in combination has the advantage of greater patient compliance and convenience, with the added assurance that the appropriate dosage of both drugs is administered, plus assured compatibility of ingredients when both types of drugs are in the same formulation and, particularly, that the correct volume of drug is delivered and retained.

The relative potency of corticosteroids depends on the molecular structure, concentration and release from the vehicle.

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

Ocular corticosteroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe where the inherent risk of corticosteroids use in certain 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.

The particular anti-infective drug in this product is active against the following common bacterial eye pathogens: Staphylococcus aureus, Escherichia coli, Haemophilus influenzae, Klebsiella/Enterobacter species, Neisseria species, and Pseudomonas aeruginosa.

This product does not provide adequate coverage against: Serratia marcescens and streptococci, including Streptococcus pneumoniae.

CONTRAINDICATIONS
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension is contraindicated in most viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension is supplied as a sterile ophthalmic suspension in a white, low density polyethylene extended LLDPE drop tip bottle with a white, polypropylene cap. Storage: Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension is not for injection. It should not be injected directly into the anterior chamber of the eye.

PRECAUTIONS

General

Instruct the patient to use the medication only as directed by his or her physician. Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and other appropriate, fluorescein staining. If signs of inflammation fail to improve after two days, the patient should be reevaluated.

As fungal infections of the cornea are particularly prone to develop coincidentally with long-term corticosteroid applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.

If this product is used for 10 days or longer, IOP should be monitored (see WARNINGS). Prolonged use of topical anti-bacterial agents may give rise to overgrowth of nonresistant organisms including fungi.

Information for Patients

If inflammation or pain persists longer than 48 hours or becomes aggravated, the patient should be advised to discontinue use of the medication and consult a physician immediately.

This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the bottle tip to eyelids or to any other surface. The use of this bottle by more than one person may spread infection. Keep bottle tightly closed when not in use. Keep out of reach of children.

Patients should be advised that their vision may be temporarily blurred following dosing with Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension. Care should be exercised in operating machinery or driving a motor vehicle.

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Pregnancy

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. However, prolonged or repeated corticosteroid use during pregnancy has been associated with an increased risk of intra-uterine growth retardation. Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension 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.

Suspension 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate carcinogenic or mutagenic potential have not been conducted with polymyxin B sulfate. Treatment of human lymphocytes in vitro with neomycin increased the frequency of chromosome aberrations at the highest concentration (80 mcg/ml) tested. However, the effects of neomycin on carcinogenesis and mutagenesis in humans are unknown.

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Nursing Mothers

Systemically administered corticosteroids appear in human milk, could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients under the age of 2 years have not been established.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

Adverse reactions have occurred with corticosteroid/antibiotic/anti-infective combination drugs which can be attributed to the corticosteroid component, the antibiotic 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 ingredient are allergic reactions. The reactions due to the corticosteroid component are: elevation of IOP with possible development of glaucoma, and infrequent optic nerve damage; posterior subcapsular cataract formation; and delayed wound healing. Corticosteroid-containing preparations have also been reported to cause perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, and conjunctival hyperemia have occasionally been reported following use of steroids.

Additional adverse reactions identified from post marketing use include ulcerative keratitis, headache, and Stevens-Johnson syndrome.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC, at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

HOW SUPPLIED

Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension, USP is supplied as a sterile ophthalmic suspension in a white, low density polyethylene extended LLDPE drop tip bottle with a white, polypropylene cap.

5 mL in 10 mL bottle. (NDC 24308-830-06)


Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA

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