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-infective steroid combination in a sterile suspension for topical application. The active ingredient, Dexamethasone, is represented by the following structural formula:

\[
\text{Dexamethasone} = \text{C}_{21}\text{H}_{29}\text{O}_{3}\text{S}_{2}
\]

It has a potency equivalent to not less than 600 micrograms of neomycin base per milligram, calculated on an anhydrous basis. The structural formula is:

\[
\text{Neomycin} = \text{C}_{22}\text{H}_{27}\text{N}_{7}\text{O}_{8}\text{S}_{2}
\]

It has a potency of not less than 6,000 neomycin B units per milligram, calculated on an anhydrous basis. The structural formula is:

\[
\text{Polymyxin B} = \text{C}_{63}\text{H}_{118}\text{N}_{25}\text{O}_{26}\text{S}_{2}
\]

Each mL contains: ACTIVES: Neomycin Sulfate (equivalent to 3.5 mg neomycin), Polymyxin B Sulfate equal to 10,000 Polymyxin B units, Dexamethasone 1 mg (0.1%), INACTIVES: Sodium Chloride, Hypromellose, Polysorbate 20, Purified Water. Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (3.5 – 6.0).

HYDROLOGIC AND ORAL:
Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (3.5 – 6.0).

Chemical Name: Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11β,16α)-. Neomycin Sulfate is the sulfated salt of neomycin B and C which are produced by the growth of Streptomyces fradiae Waksman (Fam. Streptomycetaceae). It has a potency equivalent to not less than 100 micrograms of neomycin base per milligram, calculated on an anhydrous basis. The structural formula is:

\[
\text{Neomycin} = \text{C}_{22}\text{H}_{27}\text{N}_{7}\text{O}_{8}\text{S}_{2}
\]

Polymer B Sulfate is the sulfated salt of polymyxin B and B, which are produced by the growth of Bacillus polymyxa (Flavobacterium) Migula (Fam. Bacillaceae). It has a potency of not less than 8,000 Polymyxin B units per milligram, calculated on an anhydrous basis. The structural formula is:

\[
\text{Polymyxin B} = \text{C}_{63}\text{H}_{118}\text{N}_{25}\text{O}_{26}\text{S}_{2}
\]

CLINICAL PHARMACOLOGY:
Corticosteroids suppress the inflammatory response to a variety of agents and thereby delay or slow healing. Since corticosteroids may inhibit the body’s defense mechanism against infection, a concomitant antiinfective 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 assumed 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 ocular infection exists.

Ocular corticosteroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe where infection exists.

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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, Neisseria gonorrhoeae, Klebsiella/Enterobacter species, Neisseria species, and Pseudomonas aeruginosa.

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

CONTRAINDICATIONS:
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension is contraindicated in most virulent diseases of the cornea and conjunctiva, including herpetic 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.

REFERENCES:
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension is not for injection. It should never be injected intraocularly, nor should it be directly introduced into the anterior chamber of the eye.

Warnings:
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension is not for injection. It should never be injected intraocularly, nor should it be directly introduced into the anterior chamber of the eye.

Acute purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication. Acute purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication.

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.

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Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension is supplied in a controlled drop tip bottle with a white cap in the following size:

5 mL - NDC 24208-830-60

Storage:


DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

Please see ONE-PIECE leaflet for full prescribing information.