Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension USP (Sterile)

DESCRIPTION
Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension USP is a sterile antibacterial and anti-inflammatory suspension for otic use.

Neomycin Sulfate is the sulfated salt of neomycin B and C, which are produced by the growth of Streptomyces tenebrarius Waksman (Fam. Streptomycetaceae). It has a potency equivalent of not less than 600 micrograms of neomycin standard per milligram, calculated on an anhydrous basis. The structural formulae are:

\[
\text{Neomycin B: } \text{R} = \text{H} \\
\text{Neomycin C: } \text{R} = \text{CH}_2\text{NH}_2
\]

Polymyxin B Sulfate is the sulfated salt of polymyxin B, and P, which are produced by the growth of Bacillus polymyxa (Prazmowski). Migula (Fam. Bacillaceae). It has a potency of not less than 6,000 polymyxin B units per milligram, calculated on an anhydrous basis. The structural formulae are:

\[
\text{Polymyxin B1: } \text{R} = (+) - 5-\text{ethylheptyl} \\
\text{Polymyxin B2: } \text{R} = 5-\text{ethylhexyl}
\]

Hydrocortisone is a 11-dehydrocorticosterone 6α,17,21-trihydroxy-4-ene-3β,20-diol, is an anti-inflammatory hormone. Its structural formula is:

\[
\text{C}_{22}\text{H}_{29}\text{O}_5 \quad \text{Mw} \text{~} 342.47
\]

Each mL contains:

- ACTIVES: Hydrocortisone, 10 mg (Rx)
- Neomycin Sulfate equivalent to 3.5 mg neomycin base
- Polymyxin B Sulfate, equivalent to 10,000 polymyxin B units

\[
\text{ACTION:} \text{Corticosteroids are potent anti-inflammatory agents. Neomycin and Polymyxin B sulfates together provide action against specific organisms susceptible to them.}
\]

CLINICAL PHARMACOLOGY

Corticosteroids inhibit the inflammatory response to a variety of agents and may delay healing. Since corticosteroids may inhibit the body's defense mechanisms against infection, a concurrent antimicrobial drug may be used when this inhibition is considered to be clinically significant in a particular case.

The anti-infective components in the combination are included to provide action against specific organisms susceptible to them. Neomycin sulfates and polymyxin B sulfates together are considerate active against the following microorganisms: Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, and Bacteroides fragilis. The product does not provide adequate coverage against certain organisms and should be used in conjunction with other antimicrobials.

INDICATIONS AND USAGE

For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the antibacterial activities of neomycin and polymyxin B sulfates and hydrocortisone ointment suspension.

CONTRAINdications
This product is contraindicated in those individuals who have shown hypersensitivity to any of its components, and in herpes simplex, staphylococcal, and streptococcal infections.

WARNINGS
Neomycin can induce permanent sensorineural hearing loss due to cochlear damage, mainly destruction of hair cells in the organ of Corti. The risk is greater in prolonged use. Therapy should be limited to 10 consecutive days (see PRECAUTIONS: General).

Patients being treated with neomycin containing products containing neomycin should be under close clinical observation. Neomycin and polymyxin B sulfates and hydrocortisone ointment suspension should not be used in any patient with a perforated tympanic membrane.

Discontinue promptly if irritation occurs.

Neomycin sulfates may cause ototoxic sensitization. A precise incidence of hypersensitivity reactions (primarily skin rash) due to topical neomycin is not known.

When using neomycin-containing products to control secondary infection in the chronic dermatoses, such as chronic ulcers or diabetic ulcers, it should be borne in mind that the skin in these conditions is more liable than is normal skin to become sensitized to neomycin. A precise incidence of hypersensitivity reactions (primarily skin rash) due to topical neomycin is not known.

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