DESCRIPTION:
Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution, USP, is a sterile antibacterial and anti-inflammatory solution for otic use.

Each mL contains: ACTIVES: Neomycin sulfate equivalent to 3.5 mg neomycin base, polymyxin B sulfate equivalent to 10,000 polymyxin B units, and hydrocortisone 10 mg (1%). INACTIVES: Propylene Glycol, Hydrochloric Acid, Potassium Metabisulfite, Cupric Sulfate, Glycerin, Purified Water. The pH range is 2.0 to 4.5.

Neomycin sulfite is the sulfite salt of neomycin B and C, which are produced by the growth of Streptomyces fradiae and Streptomyces kanamyceticus, respectively. It has a potency of not less than 600 micrograms of neomycin standard per milligram, calculated on an anhydrous basis. The structural formulae are:

Polymyxin B sulfates is the sulfite salt of polymyxin B1 to B6, which are produced by the growth of Bacillus polymyxa (Prazmowski) 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 formulae are:

GENERAL
PRECAUTIONS:
Neomycin contains sulfite, a substance that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

Sulfite sensitivity is manifested mainly in severe asthmatic episodes in certain susceptible people. The use of sulfites should be avoided for the patient thereafter. The product if they are observed. These symptoms regress quickly on withdrawing the medication. Neomycin-containing applications should be used if the external auditory canal disorder is suspected or known to be due to cutaneous viral infection (for example, herpes simplex virus or varicella zoster virus).

CONTRAINDICATIONS:
This product is contraindicated in those individuals who have shown hypersensitivity to any of its components. This product should not be used if the external auditory canal disorder is suspected or known to be due to cutaneous viral infection (for example, herpes simplex virus or varicella zoster virus).

WARNINGS:
Neomycin can induce permanent sensorineural hearing loss due to cochlear damage, mainly destruction of hair cells in the organ of Corti. The risk of toxicity is greater with prolonged use; therefore, treatment should be limited to 10 consecutive days (see PRECAUTIONS - General). Patients being treated with eardrops containing neomycin should be under close clinical observation. Due to its acidity, which may cause burning and stinging, Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution should not be used in any patient with a perforated tympanic membrane.

INDICATIONS AND USAGE:
For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the antibiotics.

CLINICAL PHARMACOLOGY:
Corticoids suppress the inflammatory response to a variety of agents and may delay healing. Since corticoids may inhibit the body's defense mechanisms against infection, a concomitant 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 sulfite and polymyxin B sulfates together are considered active against the following microorganisms: 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 streptococci, including Streptococcus pneumoniae.

The relative potency of corticosteroids depends on the molecular structure, concentration, and release from the vehicle. The antibiotics contained in this combination act against a variety of aerobic and anaerobic streptococci, hemolytic streptococci, Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, and Neisseria species. Neomycin and polymyxins are bactericidal agents which are effective against most aerobic Gram-negative bacilli and some aerobic Gram-positive cocci.

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DESCRIPTION:
Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution, USP (Sterile) Rx only FOR USE IN EARS ONLY
Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution is supplied in a white plastic dropper bottle in the following size:

10 mL - NDC 24208-631-10

HOW SUPPLIED:

Rx only

DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.

KEEP OUT OF REACH OF CHILDREN.

REFERENCES:
2. Leyden JJ, Kligman AM. Contact dermatitis to neomycin sulfate. JAMA 1979; 242: 1276-1278

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

Prod. No. 10009

9072205 (Folded) 9072205 (Flat)

Revised August 2018

Información para Pacientes: Evite contaminar el aplicador con material del oído, las manos o otras fuentes. Puede ser necesario evitar el uso del producto si se detecta una sensibilización al principio.

No use el producto en los ojos.

Pruebas de laboratorio: Sistémicos de niveles excesivos de hidrocortisona pueden aumentar la velocidad de la reducción de la circulación e infusión y un descenso en la excreción renal de 17-ketosteroides.

Carcinogenicidad, Mutagenicidad, Impregnación de fertilidad: Estudios largos en animales (ratas, ratas, concurrida) no mostraron ninguna evidencia de carcinogenicidad atribuible a la administración de corticosteroides.

Pregnancy: Teratogenic effects:怀孕期间可能发生的副作用。Concepción después de la aplicación tópica: Adverse reactions that have occurred with topical use of antibiotic combinations including neomycin and polymyxin B. exact incidence figures are not available since no denominator of treated patients is available. The reaction occurring most often is an allergic sensitization. In one clinical study, using a 20% neomycin patch, neomycin-induced allergic skin reactions occurred in two of 2,175 (0.09%) individuals in the general population.5 In another study, the incidence was found to be approximately 1.5%.7 The following local adverse reactions have been reported with topical corticosteroids, especially under occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. Stinging and burning have been reported when this product has gained access to the middle ear.

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.

ADVERSE REACTIONS:

Neomycin occasionally causes skin sensitization. Ototoxicity and nephrotoxicity have also been reported (see WARNINGS). Adverse reactions that have occurred with topical use of antibiotic combinations including neomycin and polymyxin B. exact incidence figures are not available since no denominator of treated patients is available. The reaction occurring most often is an allergic sensitization. In one clinical study, using a 20% neomycin patch, neomycin-induced allergic skin reactions occurred in two of 2,175 (0.09%) individuals in the general population.5 In another study, the incidence was found to be approximately 1.5%.7 The following local adverse reactions have been reported with topical corticosteroids, especially under occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria. Stinging and burning have been reported when this product has gained access to the middle ear.

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.

DOSAGE AND ADMINISTRATION:

Therapy with this product should be limited to 10 consecutive days. The external auditory canal should be thoroughly cleansed and dried with a sterile cotton applicator.

For adults, four drops of the solution should be instilled into the affected ear 3 or 4 times daily. For infants and children, three drops are suggested because of the smaller capacity of the ear canal.

The patient should lie with the affected ear upward and then the drops should be instilled. This position should be maintained for 5 minutes to facilitate penetration of the drops into the ear canal.

Repeat, if necessary, for the opposite ear.

If preferred, a cotton wick may be inserted into the canal and then the cotton may be saturated with the solution. This wick should be kept moist by adding further solution every 4 hours. The wick should be replaced at least once every 24 hours.

HOW SUPPLIED:

Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution, USP is supplied in a white plastic dropper bottle in the following size: 10 mL - NDC 24208-631-10


Rx only

Securely tighten cap between uses.