

NEO-POLYCIN- neomycin and polymyxin b sulfates and bacitracin zinc ointment

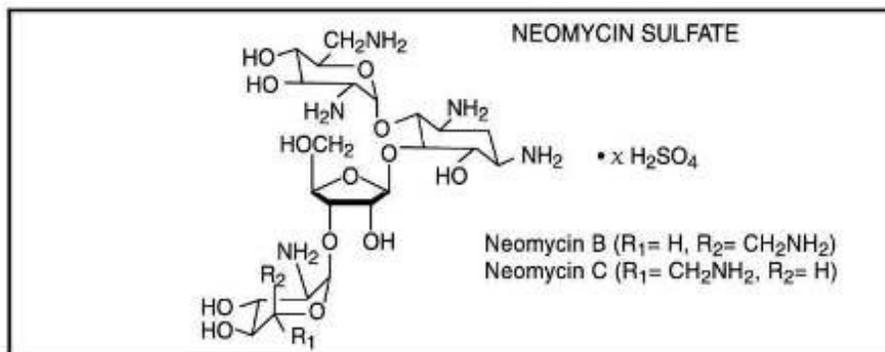
Rebel Distributors Corp

NEO-POLYCIN

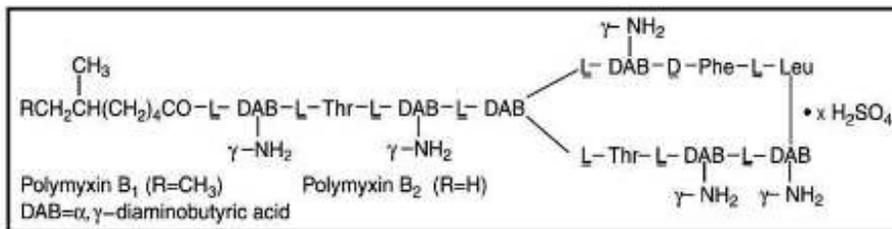
DESCRIPTION:

Neomycin and polymyxin B sulfates and bacitracin zinc ophthalmic ointment is a sterile antimicrobial ointment for ophthalmic use. Each gram contains: neomycin sulfate equivalent to 3.5 mg neomycin base, polymyxin B sulfate equivalent to 10,000 polymyxin B units, bacitracin zinc equivalent to 400 bacitracin units in a white petrolatum and mineral oil base.

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



Polymyxin B sulfate is the sulfate salt of polymyxin B₁ and B₂, 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 mg, calculated on an anhydrous basis. The structural formulae are:

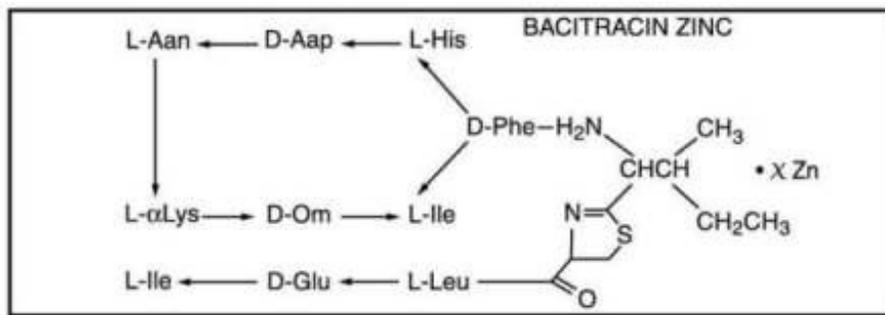


Bacitracin zinc is the zinc salt of bacitracin, a mixture of related cyclic polypeptides (mainly bacitracin A) produced by the growth of an organism of the *licheniformis*

group of

Bacillus subtilis

var Tracy. It has a potency of not less than 40 bacitracin units per mg. The structural formula is:



CLINICAL PHARMACOLOGY:

A wide range of antibacterial action is provided by the overlapping spectra of neomycin, polymyxin B sulfate, and bacitracin.

Neomycin is bactericidal for many gram-positive and gram-negative organisms. It is an aminoglycoside antibiotic which inhibits protein synthesis by binding with ribosomal RNA and causing misreading of the bacterial genetic code.

Polymyxin B is bactericidal for a variety of gram-negative organisms. It increases the permeability of the bacterial cell membrane by interacting with the phospholipid components of the membrane.

Bacitracin is bactericidal for a variety of gram-positive and gram-negative organisms. It interferes with bacterial cell wall synthesis by inhibition of the regeneration of phospholipid receptors involved in peptidoglycan synthesis.

Microbiology:

Neomycin sulfate, polymyxin B sulfate, and bacitracin zinc together are considered active against 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*.

INDICATIONS AND USAGE:

Neo-Polycin™ Ophthalmic Ointment is indicated for the topical treatment of superficial infections of the external eye and its adnexa caused by susceptible bacteria. Such infections encompass conjunctivitis, keratitis, and keratoconjunctivitis, blepharitis and blepharoconjunctivitis.

CONTRAINDICATIONS:

Neo-Polycin™ Ophthalmic Ointment is contraindicated in individuals who have shown hypersensitivity to any of its components.

WARNINGS:

NOT FOR INJECTION INTO THE EYE. Neomycin and polymyxin B sulfates and bacitracin zinc ophthalmic ointment should never be directly introduced into the anterior chamber of the eye. Ophthalmic ointments may retard corneal wound healing. 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: General**).

PRECAUTIONS:

General:

As with other antibiotic preparations, prolonged use of neomycin and polymyxin B sulfates and bacitracin zinc ophthalmic ointment may result in overgrowth of nonsusceptible organisms including fungi. If superinfection occurs, appropriate measures should be initiated. Bacterial resistance to neomycin and polymyxin B sulfates and bacitracin zinc ophthalmic ointment may also develop. If purulent discharge, inflammation, or pain becomes aggravated, the patient should discontinue use of the medication and consult a physician. There have been reports of bacterial keratitis associated with the use of topical ophthalmic products in multiple-dose containers which have been inadvertently contaminated by patients, most of whom had a concurrent corneal disease or a disruption of the ocular epithelial surface (see **PRECAUTIONS: Information for Patients**). Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: Kanamycin, paromomycin, streptomycin, and possibly gentamicin.

Information for Patients :

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye, eyelid, fingers, or any other surface. The use of this product by more than one person may spread infection. Patients should also be instructed that ocular products, if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated products (see **PRECAUTIONS: General**). If the condition persists or gets worse, or if a rash or allergic reaction develops, the patient should be advised to stop use and consult a physician. Do not use this product if you are allergic to any of the listed ingredients. Keep tightly closed when not in use. Keep out of reach of children.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

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

Pregnancy:

Teratogenic Effects: Pregnancy Category C.

Animal reproduction studies have not been conducted with neomycin sulfate, polymyxin B sulfate or bacitracin. It is also not known whether neomycin and polymyxin B sulfates and bacitracin zinc

ophthalmic ointment can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Neomycin and polymyxin B sulfates and bacitracin zinc ophthalmic ointment should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when neomycin and polymyxin B sulfates and bacitracin zinc ophthalmic ointment is administered to a nursing woman.

Pediatric Use:

Safety and effectiveness in pediatric patients 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 the anti-infective components of neomycin and polymyxin B sulfates and bacitracin zinc ophthalmic ointment. The exact incidence is not known. Reactions occurring most often are allergic sensitization reactions including itching, swelling, and conjunctival erythema (see **WARNINGS**). More serious hypersensitivity reactions, including anaphylaxis, have been reported rarely. Local irritation on instillation has also been reported.

To report SUSPECTED ADVERSE REACTIONS, contact Fera Pharmaceuticals, LLC at (414) 434-6604, Monday-Friday 9am-5pm EST or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION:

May be applied every 3 or 4 hours for 7 to 10 days, depending on the severity of the infection.

HOW SUPPLIED:

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

NDC 42254-302-35

Store at 20°-25°C (68°-77°F) [See USP Controlled room temperature].

Neo-Polycin is a Trademark of Fera Pharmaceuticals, LLC.

FERA

Mfd. for:

Fera Pharmaceuticals, LLC

Locust Valley, NY 11560

Repackaged by:

Rebel Distributors Corp.

Thousand Oaks, CA 91320

Principal Display Panel

Peel

Neo-Polycin
3.5gm Opth Ointment
Lot #: 000000
NDC 42254-302-35

Peel

Neo-Polycin
3.5gm Opth Ointment
Lot #: 000000
NDC 42254-302-35



PHYSICIAN PARTNER
A DIVISION OF REBEL DISTRIBUTORS CORP.

NDC 42254-302-35

Neo-Polycin

3.5gm Opth Ointment

Each gram contains: Neomycin Sulfate equivalent to 3.5mg Neomycin Base, Polymyxin B Sulfate equivalent to 10,000 Polymyxin B units, Bacitracin Zinc equivalent to 400 Bacitracin units.

White petrolatum and mineral oil base.

Product ID: SN030235

Mfr. For: Fera Pharmaceuticals, LLC Locust Valley, NY 11560

Peel

Neo-Polycin
3.5gm Opth Ointment
Lot #: 000000
NDC 42254-302-35

Peel

Neo-Polycin
3.5gm Opth Ointment
Lot #: 000000
NDC 42254-302-35

Distributed by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com
Store at controlled room temperature 15°-30°C (59°-86°F) Keep medication out of the reach of children.

NEO-POLYCIN		
neomycin and polymyxin b sulfates and bacitracin zinc ointment		
Product Information		
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source) NDC:42254-302(NDC:48102-006)
Route of Administration	OPHTHALMIC	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 U in 1 g
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 U in 1 g
Inactive Ingredients		
Ingredient Name	Strength	
MINERAL OIL (UNII: T5L8T28FGP)		
PETROLATUM (UNII: 4T6H12BN9U)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-302-35	1 in 1 CARTON		
1		3.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA060764	07/15/2011	

Labeler - Rebel Distributors Corp (118802834)**Registrant** - PSS World Medical, Inc. (101822862)**Establishment**

Name	Address	ID/FEI	Business Operations
PSS World Medical, Inc.		791528623	REPACK(42254-302)

Establishment

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	REPACK(42254-302)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	RELABEL(42254-302) , REPACK(42254-302)

Establishment

Name	Address	ID/FEI	Business Operations
SCRIPT PAK		964420108	RELABEL(42254-302) , REPACK(42254-302)

Establishment

Name	Address	ID/FEI	Business Operations
Keltman Pharmaceuticals, Inc.		362861077	REPACK(42254-302)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp.		118802834	RELABEL(42254-302) , REPACK(42254-302)