NEOMYCIN AND POLYMYXIN B SULFATES, AND BACITRACIN ZINC- neomycin sulfate, polymyxin b sulfate and bacitracin zinc ointment
MWI

---

apexa™
Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment, USP

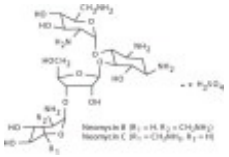
STERILE

Rx Only

DESCRIPTION:

Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment, USP is a sterile antimicrobial ointment for ophthalmic use. Each gram contains: Neomycin Sulfate (equivalent to 3.5 mg neomycin base), Polymyxin B sulfate equal to 10,000 polymyxin B units, bacitracin zinc equal to 400 bacitracin units, and white petrolatum, q.s.

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 mcg of neomycin standard per mg, calculated on an anhydrous basis. The structural formula are:



Polymyxin B sulfate is the sulfate salt of polymyxin B_1 and B_2, which are produced by the growth *of Bacillus palymyxa* (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 *lichenifoimis* 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 phospholipid synthesis.

Microbiology: Neomycin sulfate, polymyxin B sulfate, and bacitracin zinc together are considered active against the following microorganisms: Staphylococcus aureus, streptococci including Streptococcus pneumoniae, Escherichiacoli, Haemophilusinfluenzae, Klebsiella/Enterobacter species, Neisseria species, and Pseudomonas aeruginosa. The product does not provide adequate coverage against Serratia marcescens.

INDICATIONS AND USAGE:

Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment, USP 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:

Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment, USP 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 Ointment USP 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. Application 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 USP 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 USP 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 mcg/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, liter 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, USP 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, USP should be given to pregnant woman only if dearly 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, USP 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 Sulfate and Bacitracin Zinc Ophthalmic Ointment USP. 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.

DOSAGE AND ADMINISTRATION:

Apply the ointment every 3 or 4 hours for 7 to 10 days, depending on the severity of the infection.

HOW SUPPLIED:

Tube of 1/8 oz. (3.5 g) with ophthalmic tip.

NDC13985-607-03

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

apexa™
Manufactured by: Akorn Inc.
Lake Forest IL 60045

Distributed by: MWI
Boise, ID 83705

MWNP00N Rev. 10/15

Principal Display Panel Text for Container Label:

NDC 13985-607-03

Neomycin and STERILE

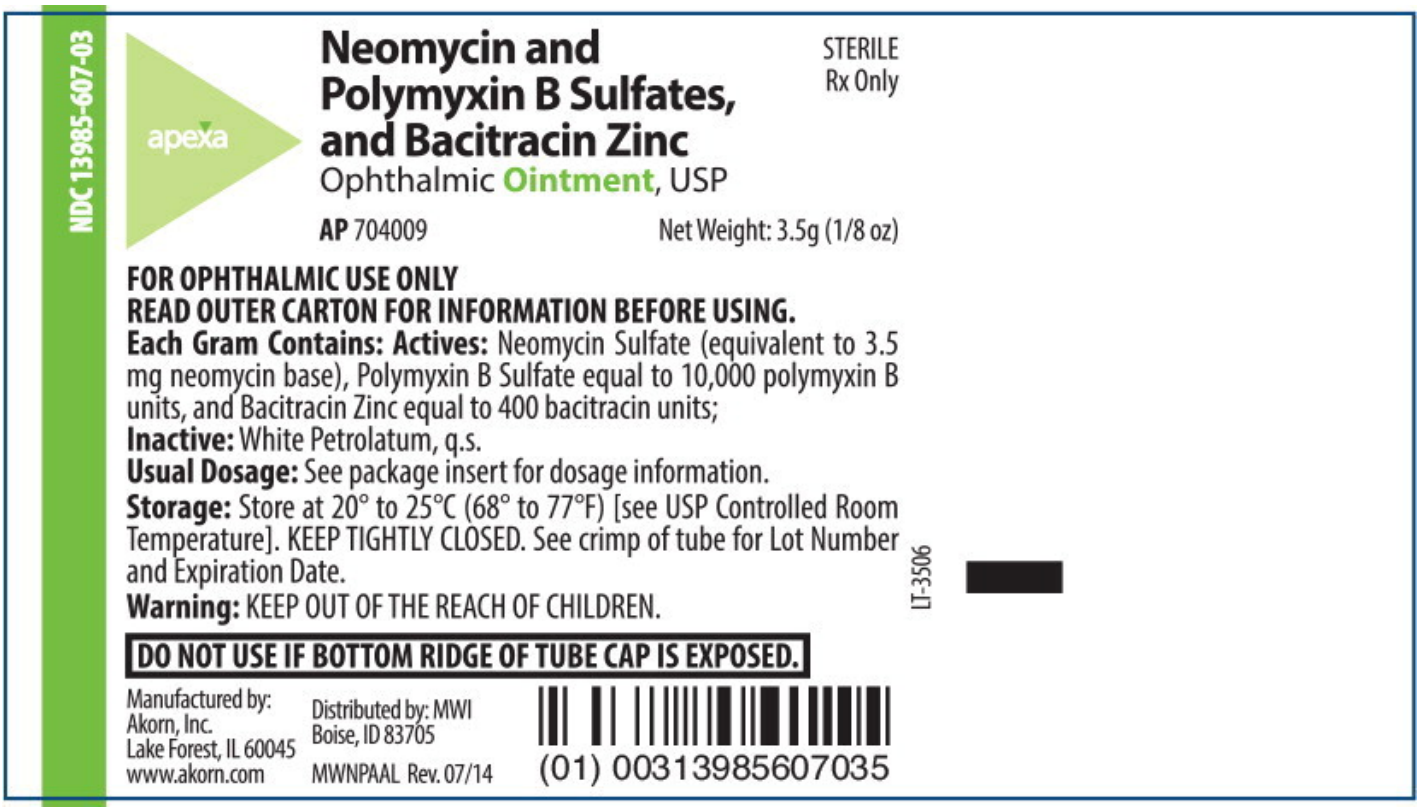
Polymyxin B Sulfates, Rx Only

and Bacitracin Zinc

Ophthalmic Ointment, USP

Apexa logo

AP 704009 Net Weight: 3.5g (1/8 oz)



Principal Display Panel Text for Carton Label:

NDC 13985-607-03

Neomycin and

Polymyxin B

Sulfates, and

Bacitracin Zinc

Ophthalmic

Ointment, USP

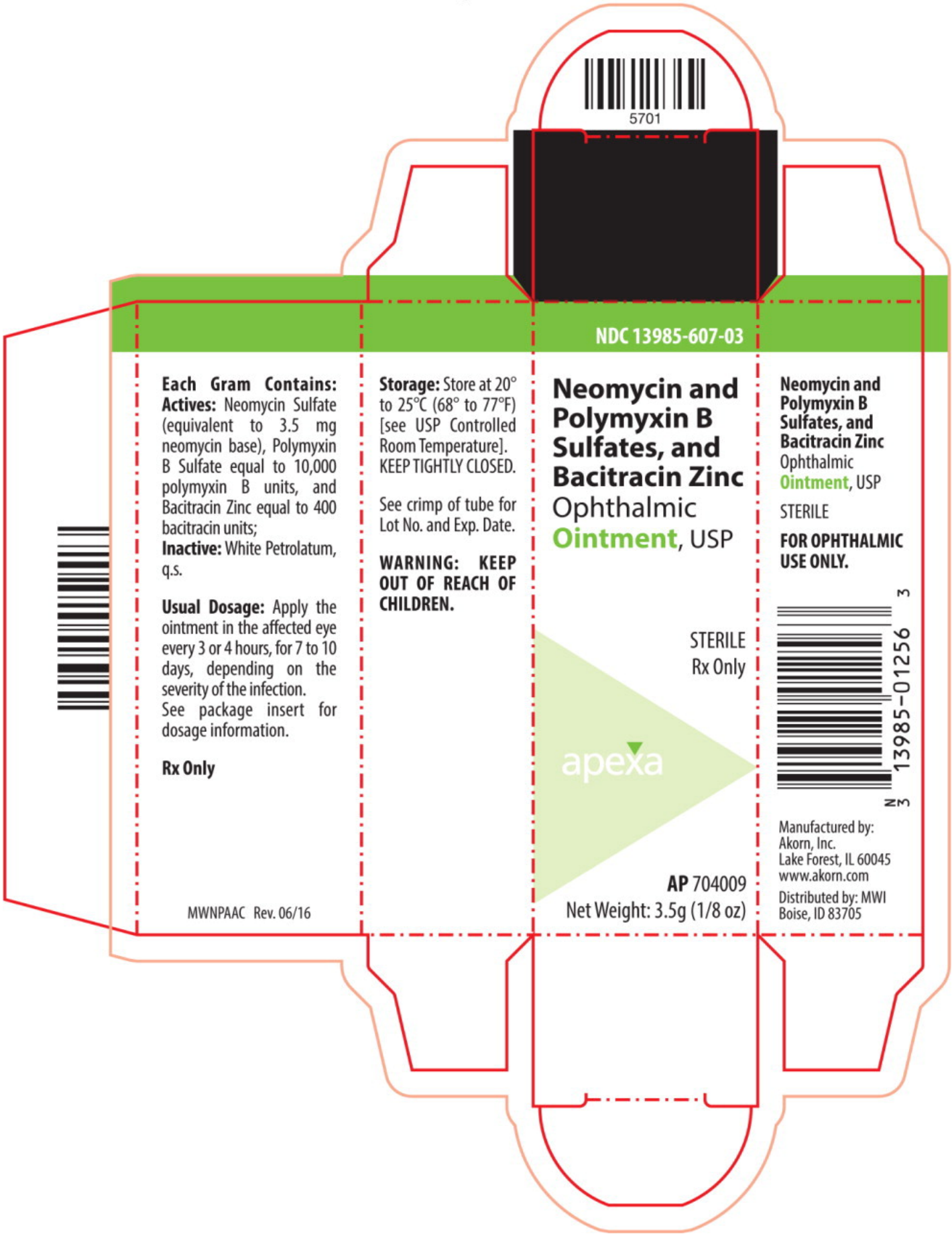
STERILE

Rx Only

Apexa logo

AP 704009

Net Weight: 3.5g (1/8 oz)


5701
NDC 13985-607-03
Each Gram Contains:
Actives: Neomycin Sulfate (equivalent to 3.5 mg neomycin base), Polymyxin B Sulfate equal to 10,000 polymyxin B units, and Bacitracin Zinc equal to 400 bacitracin units;
Inactive: White Petrolatum, q.s.
Usual Dosage: Apply the ointment in the affected eye every 3 or 4 hours, for 7 to 10 days, depending on the severity of the infection.
See package insert for dosage information.
Rx Only
MWNPAAC Rev. 06/16
Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
KEEP TIGHTLY CLOSED.
See crimp of tube for Lot No. and Exp. Date.
WARNING: KEEP OUT OF REACH OF CHILDREN.
Neomycin and Polymyxin B Sulfates, and Bacitracin Zinc
Ophthalmic Ointment, USP
STERILE
Rx Only
apexa
AP 704009
Net Weight: 3.5g (1/8 oz)
Neomycin and Polymyxin B Sulfates, and Bacitracin Zinc
Ophthalmic Ointment, USP
STERILE
FOR OPHTHALMIC USE ONLY.
N 3 13985-01256 3
Manufactured by:
Akorn, Inc.
Lake Forest, IL 60045
www.akorn.com
Distributed by: MWI
Boise, ID 83705

NEOMYCIN AND POLYMYXIN B SULFATES, AND BACITRACIN ZINC

neomycin sulfate, polymyxin b sulfate and bacitracin zinc ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:13985-607
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 [USP'U] in 1 g
Bacitracin Zinc (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I)	Bacitracin	400 [USP'U] in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Petrolatum (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:13985-607-03	1 in 1 CARTON	03/23/2015	
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065088	03/23/2015	

Labeler - MWI (019926120)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(13985-607) , ANALYSIS(13985-607) , STERILIZE(13985-607) , LABEL(13985-607) , PACK(13985-607)

Revised: 2/2022 MWI