

BACITRACIN ZINC AND POLYMYXIN B SULFATE- bacitracin zinc and polymyxin b sulfate ointment

Rebel Distributors Corp

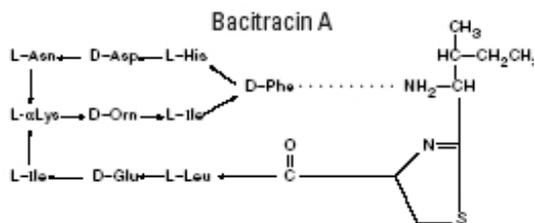
Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment USP (Sterile)

Rx only

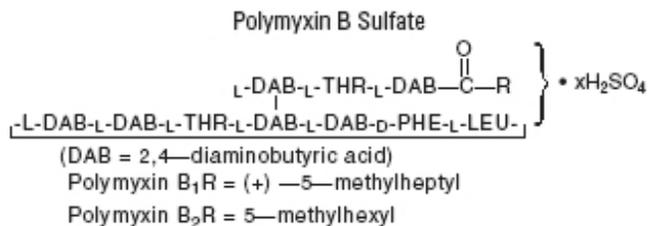
DESCRIPTION:

Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment USP is a sterile antimicrobial ointment formulated for ophthalmic use.

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 for bacitracin A is:



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:



Each Gram Contains: ACTIVES: Bacitracin Zinc equal to 500 bacitracin units and Polymyxin B Sulfate equal to 10,000 polymyxin B units; INACTIVES: White Petrolatum and Mineral Oil.

CLINICAL PHARMACOLOGY:

Polymyxin B sulfate attacks gram-negative bacilli, including virtually all strains of *Pseudomonas aeruginosa* and *Haemophilus influenzae* species.

Bacitracin is active against most gram-positive bacilli and cocci including hemolytic streptococci.

INDICATIONS AND USAGE:

For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by organisms susceptible to bacitracin zinc and polymyxin B sulfate.

CONTRAINDICATIONS:

This product is contraindicated in those individuals who have shown hypersensitivity to any of its components.

WARNINGS:

Ophthalmic ointments may retard corneal healing.

PRECAUTIONS:

As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

DOSAGE AND ADMINISTRATION:

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

FOR OPHTHALMIC USE ONLY.**HOW SUPPLIED:**

Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment USP is available in tubes with an ophthalmic tip applicator in the following size:

3.5 gram tube - NDC 42254-154-35

DO NOT USE IF CAP AND NECKRING ARE NOT INTACT.**Storage:**

Store between 15°-25°C (59°-77°F). KEEP TIGHTLY CLOSED.

KEEP OUT OF REACH OF CHILDREN.

Revised November 2007

Bausch & Lomb Incorporated

Tampa, FL 33637

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9130700 (**Folded**)

9130600 (**Flat**)

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL

Peel

Bacitracin Zinc Polymyxin B 500/10,000 Units
3.5gm Ophthalmic Oint. Rx# Master
Lot #: 000000 Exp. Date: 00/00/00
NDC 42254-154-35 AWP:\$51.40



PHYSICIAN PARTNER
A DIVISION OF REDEL DISTRIBUTORS CORP.

NDC 42254-154-35

**Bacitracin Zinc/ Polymyxin B
500/ 10,000 Units
3.5gm Ophthalmic Oint.**

Each gram contains: Bacitracin Zinc equal to 500 Bacitracin units and Polymyxin B Sulfate equal to 10,000 Polymyxin B units.

See package insert

Product ID: SB015435

Mfr. By: Bausch & Lomb Incorporated Tampa, FL 33637

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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.

BACITRACIN ZINC AND POLYMYXIN B SULFATE

bacitracin zinc and polymyxin b sulfate ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42254-154(NDC:24208-555)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN ZINC	500 in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B SULFATE	10000 in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-154-35	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	ANDA064046	04/25/2008	

Labeler - Rebel Distributors Corp (118802834)**Establishment**

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2012

Rebel Distributors Corp