

BACITRACIN ZINC AND POLYMYXIN B SULFATE - bacitracin zinc and polymyxin b sulfate ointment
STAT RX USA LLC

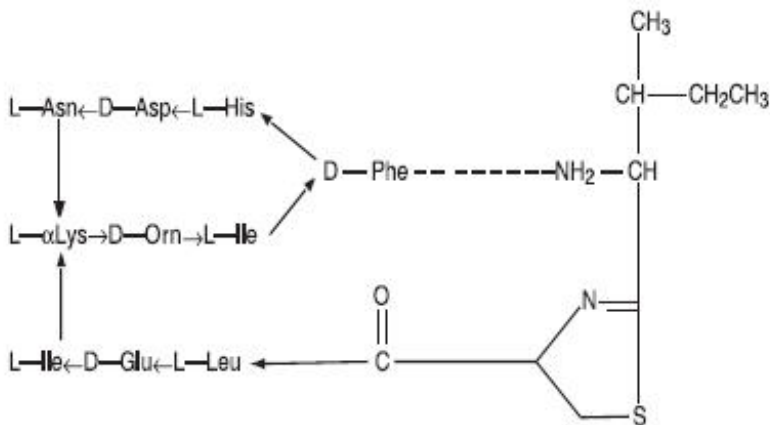
BACITRACIN ZINC AND POLYMYXIN B SULFATE ointment [Akorn, Inc.]

Rx only

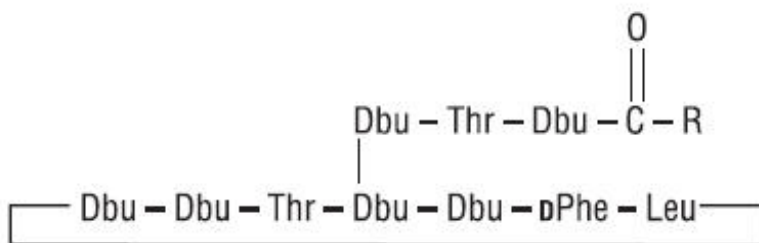
DESCRIPTION

Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment is a sterile antimicrobial ointment 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:



(Dbu = 2,4-diaminobutyric acid)
 Polymyxin B₁ R = (+)-5-methylheptyl
 Polymyxin B₂ R = 5-methylhexyl

Each gram contains: Bacitracin zinc equal to 500 bacitracin units and polymyxin B sulfate equal to 10,000 polymyxin B units, white petrolatum and mineral oil.

CLINICAL PHARMACOLOGY

Polymyxin B attacks gram-negative bacilli, including virtually all strains of *Pseudomonas aeruginosa* and *H 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.

HOW SUPPLIED

Bacitracin Zinc and Polymyxin B Sulfate ophthalmic ointment USP, sterile, each gram contains bacitracin zinc equal to 500 bacitracin units and polymyxin B sulfate equal to 10,000 polymyxin B units, in a tube of 3.5 g (1/8 oz) with ophthalmic tip.

NDC 17478-238-35

STORAGE

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

Manufactured By: Akorn, Inc.
Lake Forest, IL 60045

AKP00N
Rev. 11/08

PACKAGE LABEL - AK - POLY-BAC OPHTHALMIC OINTMENT 3.5 GRAMS

Packaged and distributed by: **STAT R_x USA** LLC Gainesville, GA 30501

Ak - Poly - Bac Opth Oint
500/10k units 3.5 g

Generic For:

NDC 16590-989-35 Prod# 989-35
 Lot# SAMPLE

Each Gram Contains: Bacitracin Zinc equal to 500
 Bacitracin units, Polymyxin B Sulfate equal to 10,000
 polymyxin B units

Mfg By: Akorn Inc.
 Lake Forest, IL 60045

NDC 17478-238-35

Mfg Lot: 0H85A
 Discard After: 07/13

BW 6/20/2011 SAMPLE

RX ONLY-KEEP OUT OF REACH OF CHILDREN

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.

BN5B5

FOR EYES



Dosage: See package insert
 Store between 59-86 degrees F

BACITRACIN ZINC AND POLYMYXIN B SULFATE

bacitracin zinc and polymyxin b sulfate ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:16590-989(NDC:17478-238)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN ZINC	500 [USP'U] in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B SULFATE	10000 [USP'U] 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:16590-989-35	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	ANDA064028	01/30/1995	

Labeler - STAT RX USA LLC (786036330)

Establishment

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	relabel, repack

Revised: 8/2011

STAT RX USA LLC