

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

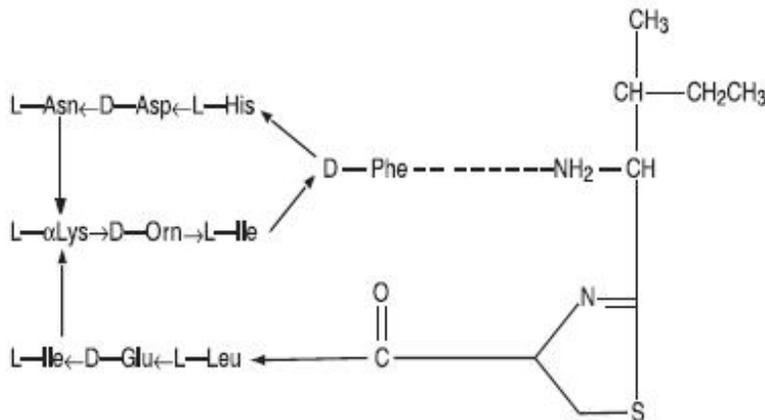
Physicians Total Care, Inc.

Rx only

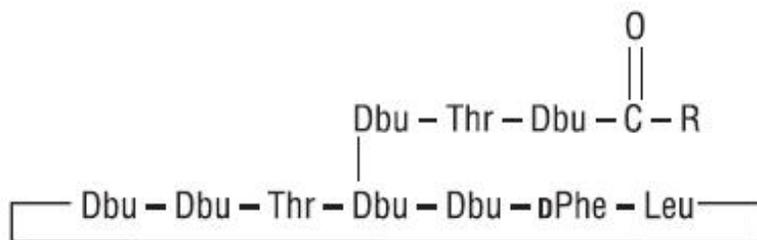
**DESCRIPTION**

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 B<sub>1</sub> and B<sub>2</sub> 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 B<sub>1</sub>      R = (+)-5-methylheptyl  
 Polymyxin B<sub>2</sub>      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 54868-1199-0

## **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

## **Relabeling of "Additional Barcode Label" by:**

Physicians Total Care, Inc.  
Tulsa, OK 74146

## **PRINCIPAL DISPLAY PANEL**

Bacitracin Zinc and Polymyxin B Sulfate ophthalmic ointment USP

3.5 g (1/8 ounce)



## BACITRACIN ZINC AND POLYMYXIN B SULFATE

bacitracin zinc and polymyxin b sulfate ointment

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:54868-1199(NDC:17478-238-35)
<b>Route of Administration</b>	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:54868-1199-0	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	11/12/2004	

**Labeler** - Physicians Total Care, Inc. (194123980)

**Establishment**

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 11/2010

Physicians Total Care, Inc.