

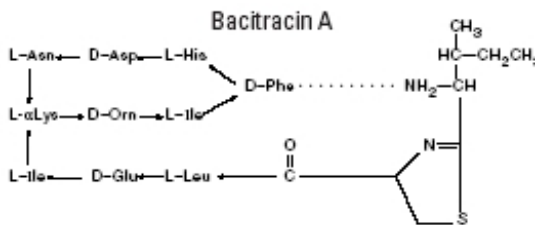
**BACITRACIN ZINC AND POLYMYXIN B SULFATE- bacitracin zinc and polymyxin b sulfate ointment**  
**Preferred Pharmaceuticals Inc.**

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**Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment, USP (Sterile)**  
**Rx only**

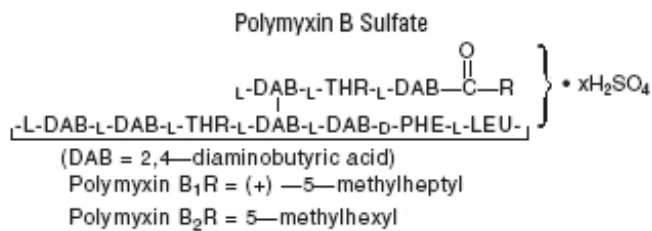
**DESCRIPTION**

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/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/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:** Mineral Oil and White Petrolatum.

**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.

## **ADVERSE REACTIONS**

**To report SUSPECTED ADVERSE REACTIONS, contact Bausch & Lomb Incorporated at 1-800-321-4576 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## **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 g tube (NDC68788-7599-3)

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

**Storage**

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

**Keep out of reach of children.**

**Distributed by:**

Bausch + Lomb, a division of Bausch Health US, LLC

Bridgewater, NJ 08807 USA

**Manufactured by:**

Bausch & Lomb Incorporated

Tampa, FL 33637 USA

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Revised: February 2020

9130703 **(Folded)**

9130603 **(Flat)**

**Relabeled By: Preferred Pharmaceuticals Inc.**

**PRINCIPAL DISPLAY PANEL**

**NDC 24208-555-55**

**Bacitracin Zinc and  
Polymyxin B Sulfate**

**Ophthalmic  
Ointment, USP**

(Sterile)

**FOR OPHTHALMIC USE ONLY**

**Rx only**

**Net Wt. 1/8 oz  
(3.5 g)**

BAUSCH + LOMB

**Relabeled By: Preferred Pharmaceuticals Inc.**

# Bacitracin Zinc and Poly. B Sulfate Opth. Ointment

Generic for Polysporin Ointment  
Each gram contains Bacitracin Zinc eq. to 500 bacitracin units / Polymyxin B Sulfate eq. to 10,000 polymyxin B units

Pkg Size: Exp Date:  
Lot#: Batch#: Ins:

Mfg: Bausch & Lomb Pharmaceuticals; Tampa, FL  
Prod#:

**Warning**  
For ophthalmic use only. Read enclosed insert for additional information. Store between 15°-30° C (59°-86° F). Keep out of reach of children. Rx Only. Keep tightly closed. Do not use if cap and necking are not intact.



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed

Bacitracin Zinc and Poly. B Sulfate Opth. Ointment  
Qty: Ins:  
Lot#: Bat#:

Log

Directions English  
For external use only.

Instrucciones Español:  
Para exte ramente  
aplique

Prod# (NDC):  
Bacitracin Zinc and Poly. B Sulfate Opth. Ointment  
Qty: Ins:  
Lot#: Bat#:  
Prod# (NDC):

Chart

Bacitracin Zinc and Poly. B Sulfate Opth. Ointment  
Qty: Ins:  
Insurance NDC:  
Lot#: Bat#:

Billing

Bacitracin Zinc and Poly. B Sulfate Opth. Ointment  
Qty: Ins:  
Lot#: Bat#:  
Prod# (NDC):

Patient

## 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:68788-7599(NDC:24208-555)
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BACITRACIN ZINC</b> (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USP'U] in 1 g
<b>POLYMYXIN B SULFATE</b> (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ.07J96K)	POLYMYXIN B	10000 [USP'U] in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7599-3	1 in 1 CARTON	03/27/2020	
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA064046	03/27/2020	

**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals Inc. (791119022)

### Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-7599)

Revised: 3/2022

Preferred Pharmaceuticals Inc.