

**BACITRACIN ZINC AND POLYMYXIN B SULFATE- bacitracin zinc and polymyxin b sulfate ointment**  
**A-S Medication Solutions**

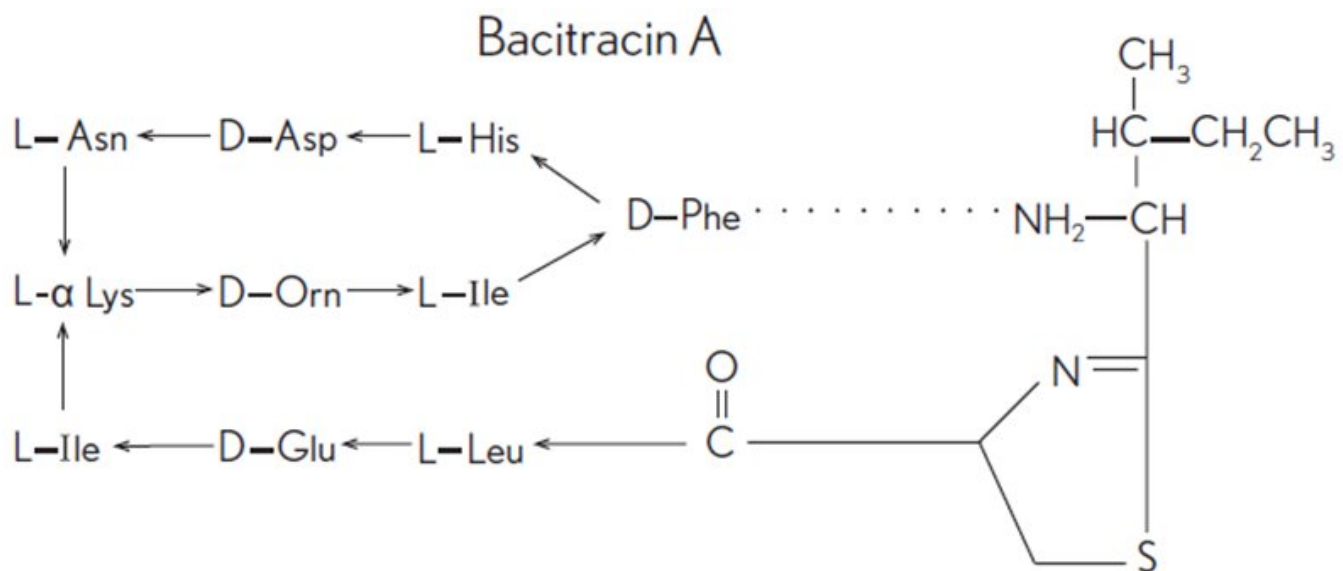
**Bacitracin Zinc and Polymyxin B Sulfate**  
**Ophthalmic Ointment, USP**  
**(Sterile)**

**Rx only**

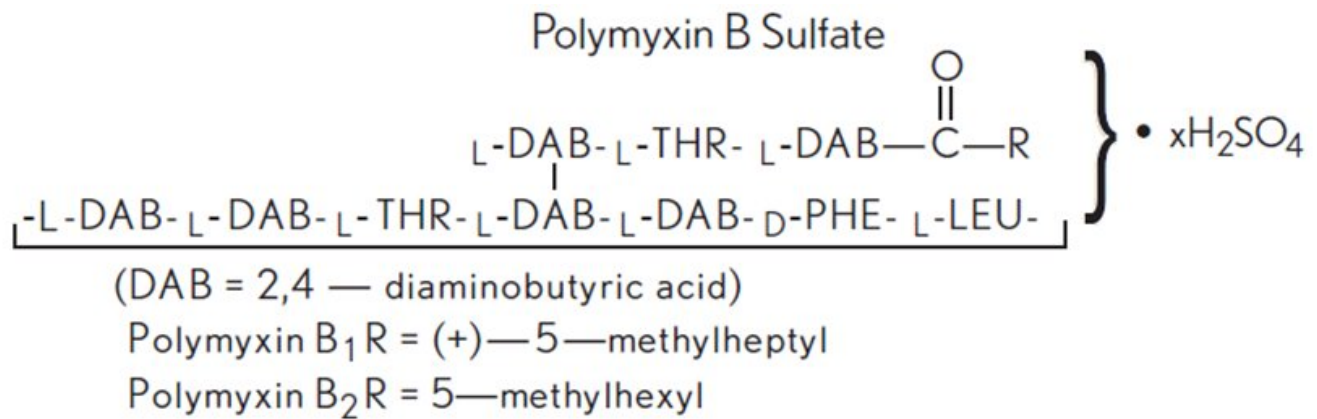
**DESCRIPTION**

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 1-800-553-5340 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

Product: 50090-7189

NDC: 50090-7189-0 3.5 g in a TUBE / 144 in a CASE

## Bacitracin Zinc and Polymyxin B Sulfate



## BACITRACIN ZINC AND POLYMYXIN B SULFATE

bacitracin zinc and polymyxin b sulfate ointment

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50090-7189(NDC:24208-555)
Route of Administration	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BACITRACIN ZINC</b> (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I)	BACITRACIN	500 [USP'U] in 1 g
<b>POLYMYXIN B SULFATE</b> (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 [USP'U] in 1 g

## Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFINUM LIQUIDUM (UNII: T5L8T28FGP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-7189-0	144 in 1 CASE	07/02/2024	
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	ANDA064046	04/25/2008	

**Labeler -** A-S Medication Solutions (830016429)

## Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-7189)

Revised: 1/2026

A-S Medication Solutions