

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

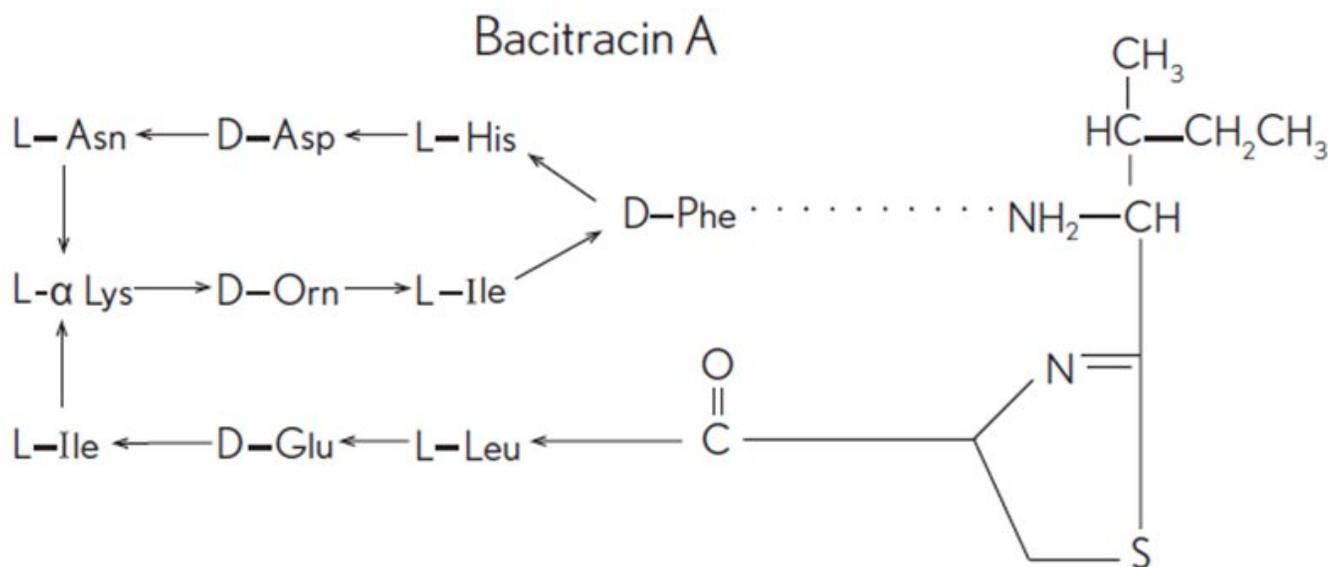
Bacitracin Zinc and Polymyxin B Sulfate
Ophthalmic Ointment, USP
(Sterile)

Rx only

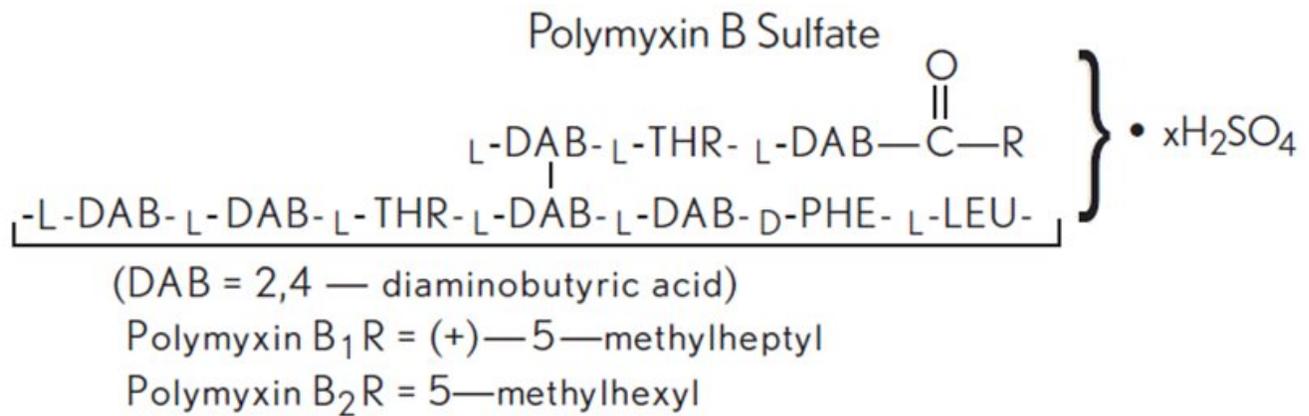
DESCRIPTION

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 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/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.

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: 50090-3274

NDC: 50090-3274-0 3.5 g in a TUBE / 1 in a CARTON

Storage

Store between 15°-25°C (59°-77°F). KEEP TIGHTLY CLOSED. Keep out of reach of children Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC Bridgewater, NJ 08807 USA

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:50090-3274(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 | 500 [USP'U] in 1 g |
| POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ 07J96K) | POLYMYXIN B | 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:50090-3274-0 | 1 in 1 CARTON | 11/21/2017 | |
| 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(50090-3274) |

Revised: 7/2023

A-S Medication Solutions