

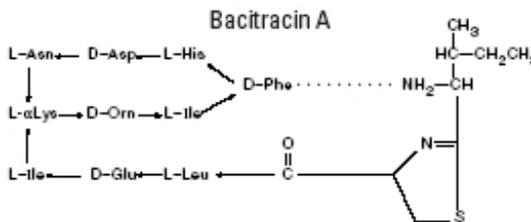
**BACITRACIN ZINC AND POLYMYXIN B SULFATE- bacitracin zinc and polymyxin b sulfate ointment**  
**NuCare Pharmaceuticals, Inc.**

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

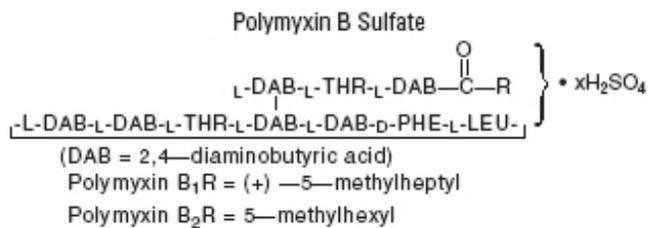
**DESCRIPTION**

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:

tube of 3.5g -NDC 68071-5267-3

## **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

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9130603 **(Flat)**

**PRINCIPAL DISPLAY PANEL**
**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:68071-5267(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 |
|--------------------------------|----------|
| MINERAL OIL (UNII: T5L8T28FGP) |          |
| PETROLATUM (UNII: 4T6H12BN9U)  |          |

## Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68071-5267-3 | 3.5 g in 1 BOX; Type 0: Not a Combination Product | 06/03/2020           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA064046                               | 04/25/2008           |                    |

**Labeler** - NuCare Pharmaceuticals, Inc. (010632300)

## Establishment

| Name                         | Address | ID/FEI    | Business Operations |
|------------------------------|---------|-----------|---------------------|
| NuCare Pharmaceuticals, Inc. |         | 010632300 | relabel(68071-5267) |

Revised: 12/2024

NuCare Pharmaceuticals, Inc.