

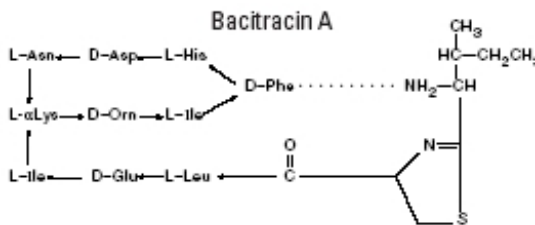
BACITRACIN ZINC AND POLYMYXIN B SULFATE- bacitracin zinc and polymyxin b sulfate ointment
NuCare Pharmaceuticals, Inc.

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

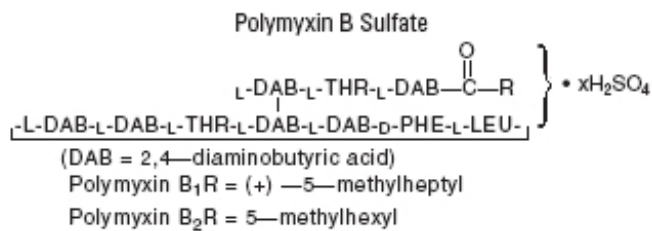
DESCRIPTION

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 1-800-321-4576 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

Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment, USP is available in tubes with an ophthalmic tip applicator in the following size:

Box 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

9130703 **(Folded)**

9130603 **(Flat)**

PRINCIPAL DISPLAY PANEL

NuCare Pharmaceuticals, Inc.
 NDC: 68071-5267-3
Bacitracin Zinc/Polymyxin B Sulfate
3.5g Ophth. Oint.
 Each gram contains: Actives: Bacitracin Zinc equal to 500 Bacitracin units and Polymyxin B Sulfate equal to 10,000 Polymyxin B units
 See manufacturer's label for full list of ingredients
 Product #: R0372035
Rx Only

Bacitracin Zinc/Polymyxin B Sulfate
 Lot: 00000 NDC: 68071-5267-03
 MFR NDC: 24208-555-55 Exp.: 00-00
 Serial# 0000000002

Bacitracin Zinc/Polymyxin B Sulfate
 Lot: 00000 NDC: 68071-5267-03
 MFR NDC: 24208-555-55 Exp.: 00-00
 Serial# 0000000002

GTIN 00368071526738
 Serial# 0000000002
 Exp. Date 00-00
 LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured by: Bausch & Lomb Incorporated
 Tampa, FL 33637
 Packaged by: NuCare Pharmaceuticals, Inc.
 Orange, CA 92867

Apply every _____ times a day. _____ hours

Rev 01/01/19
 WARNING: KEEP OUT OF REACH OF CHILDREN
 STORE AT CONTROLLED TEMPERATURE 59-77°F.

BACITRACIN ZINC AND POLYMYXIN B SULFATE

bacitracin zinc and polymyxin b sulfate ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68071-5267(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
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: 7/2024

NuCare Pharmaceuticals, Inc.