

BACITRACIN ZINC AND POLYMYXIN B SULFATE- bacitracin zinc and polymyxin b sulfate ointment

Direct_Rx

BACITRACIN ZINC AND POLYMYXIN B SULFATE

Rx only

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:

[Bacitracin A (Structural Formula)]

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:

[Polymyxin B Sulfate (Structural Formula)]

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.

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.

For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by organisms susceptible to bacitracin zinc and polymyxin B sulfate.

This product is contraindicated in those individuals who have shown hypersensitivity to any of its components.

Ophthalmic ointments may retard corneal healing.

As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC, at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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

DO NOT USE IF CAP AND NECKRING ARE NOT INTACT.

Storage

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

Keep out of reach of children

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Revised: November 2017

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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72189-017(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 [USPU] in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 [USPU] 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:72189-017-35	3.5 g in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064046	07/24/2019	

Labeler - Direct_Rx (079254320)

Registrant - Direct_Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct_Rx		079254320	repack(72189-017)

Revised: 7/2019

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