

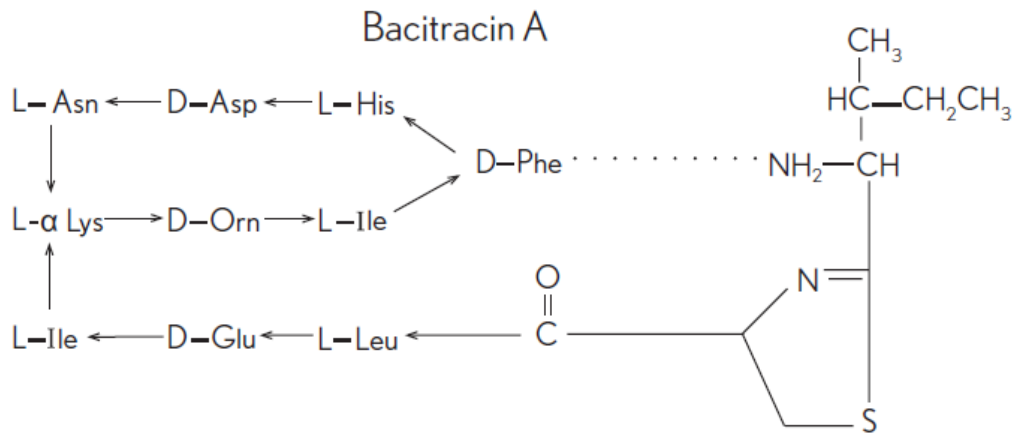
**Bacitracin Zinc and Polymyxin B Sulfate  
Ophthalmic Ointment, USP  
(Sterile)**

**Rx only**

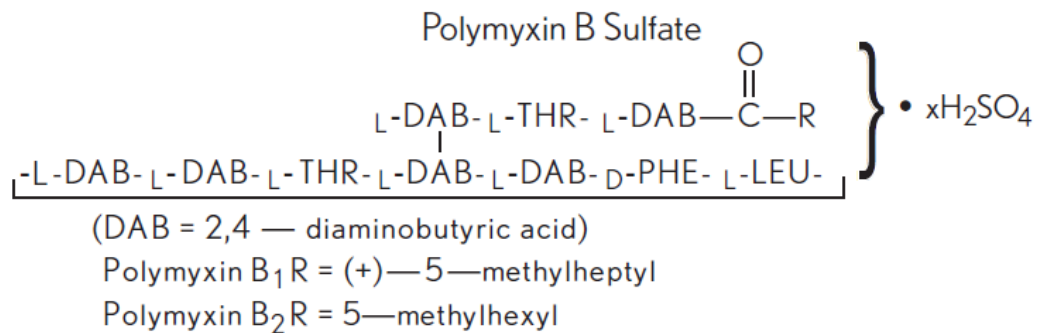
**DESCRIPTION**

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**

Bacitracin zinc and polymyxin B sulfate ophthalmic ointment, USP is available in tubes with an ophthalmic tip applicator in the following size:

NDC 24208-555-55 - 3.5 g tube

**DO NOT USE IF BOTTOM RIDGE OF TUBE CAP IS EXPOSED.**

### **Storage:**

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

**KEEP OUT OF REACH OF CHILDREN.**

### **Distributed by:**

Bausch & Lomb Americas Inc.  
Bridgewater, NJ 08807 USA

**Manufactured by:**  
Bausch & Lomb Incorporated  
Tampa, FL 33637 USA

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