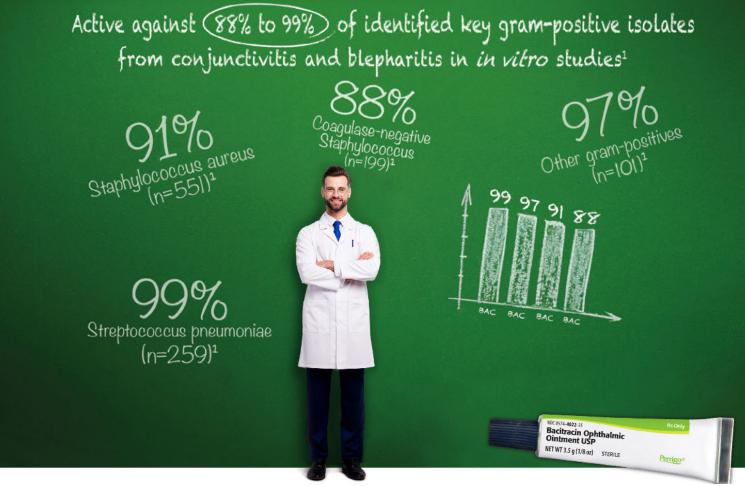
## **BACITRACIN OPHTHALMIC OINTMENT USP**



In Vitro Susceptibility Data Provided Through the University of Pittsburgh Medical Center. In Vitro Data Should Not Be Considered Representative of Clinical Efficacy<sup>1</sup>

Established therapeutic utility in blepharitis, conjunctivitis, and other superficial ocular infections caused by Bacitracin-susceptible organisms

- Excellent safety profile—low incidence of adverse events<sup>2</sup>
- Ointment provides long-lasting ocular surface contact time and greater bioavailability<sup>3</sup>
- Anti-infective efficacy in a lubricating base<sup>2</sup>
- Flexible dosing 1 to 3 times daily<sup>2</sup>
- Tier 1 pharmacy benefit status on most insurance plans<sup>4</sup>

### Indication

Bacitracin Ophthalmic Ointment is indicated for the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by Bacitracin susceptible organisms.

## Important Safety Information

This product should not be used in patients with a history of hypersensitivity to Bacitracin. Bacitracin Ophthalmic Ointment should not be used in deep-seated ocular infections or in those that are likely to become systemic. There is a low incidence of allergenicity exhibited by Bacitracin. If such reactions do occur, therapy should be discontinued.

See below for full prescribing information.

NDC Size Case Pack 0574-4022-35 3.5 g 144 / 12

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# **Bacitracin Ophthalmic Ointment USP**

STERILE Rx Only

**DESCRIPTION**: Each gram of ointment contains 500 units of Bacitracin in a low melting special base containing White Petrolatum and Mineral Oil.

**CLINICAL PHARMACOLOGY**: The antibiotic, Bacitracin, exerts a profound action against many gram-positive pathogens, including the common Streptococci and Staphylococci. It is also destructive for certain gram-negative organisms. It is ineffective against fungi.

**INDICATIONS AND USAGE**: For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by Bacitracin susceptible organisms.

**CONTRAINDICATIONS**: This product should not be used in patients with a history of hypersensitivity to Bacitracin.

**PRECAUTIONS**: Bacitracin ophthalmic ointment should not be used in deep-seated ocular infections or in those that are likely to become systemic. The prolonged use of antibiotic containing preparations may result in overgrowth of nonsusceptible organisms particularly fungi. If new infections develop during treatment appropriate antibiotic or chemotherapy should be instituted.

**ADVERSE REACTIONS**: Bacitracin has such a low incidence of allergenicity that for all practical purposes side reactions are practically non-existent. However, if such reaction should occur, therapy should be discontinued.

To report SUSPECTED ADVERSE REACTIONS, contact Padagis at 1-866-634-9120 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**DOSAGE AND ADMINISTRATION**: The ointment should be applied directly into the conjunctival sac 1 to 3 times daily. In blepharitis all scales and crusts should be carefully removed and the ointment then spread uniformly over the lid margins. Patients should be instructed to take appropriate measures to avoid gross contamination of the ointment when applying the ointment directly to the infected eye.

#### **HOW SUPPLIED:**

NDC 0574-4022-35 3.5 g (1/8 oz.) sterile tamper evident tubes with ophthalmic tip.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Manufactured For Padagis Minneapolis, MN 55427 0S400 RC J1 Rev 08-13 A R0813 Ini0813