# BACITRACIN- bacitracin ointment Rebel Distributors Corp

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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.

### **ACTION:**

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:

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.

### **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:**

3.5 g (1/8 Oz) sterile tamper proof tubes, NDC 42254-003-35.



Manufactured for:

Fera Pharmaceuticals, LLC

Locust Valley, NY 11560

FPBC00N

Rev. 08/09

Repackaged by:

**Rebel Distributors Corp** 

Thousand Oaks, CA 91320

### PRINCIPAL DISPLAY PANEL



# BACITRACIN bacitracin ointment Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:42254-003(NDC:48102-007) Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	BACITRACIN (UNII: 58 H6 RWO 521) (BACITRACIN - UNII: 58 H6 RWO 521)	BACITRACIN	500 [iU] in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
MINERAL O IL (UNII: T5L8T28FGP)		
PETROLATUM (UNII: 4T6H12BN9U)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:42254-003-35	1 in 1 CARTON			
1	3.5 g in 1 TUBE			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA061212	0 1/11/20 10			

## Labeler - Rebel Distributors Corp (118802834)

Establishment					
Name	Address	ID/FEI	Business Operations		
Rebel Distributors Corp		118802834	RELABEL, REPACK		

Revised: 11/2011 Rebel Distributors Corp