

**BACITRACIN- bacitracin ointment**  
**Padagis US LLC**

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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](http://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® by Jubilant HollisterStier General Partnership  
Kirkland, Quebec H9H 4J4 Canada

35F00 RC PH2

Rev 02-23

**PACKAGE/LABEL PRINCIPAL DISPLAY PANEL - 3.5 g Carton**

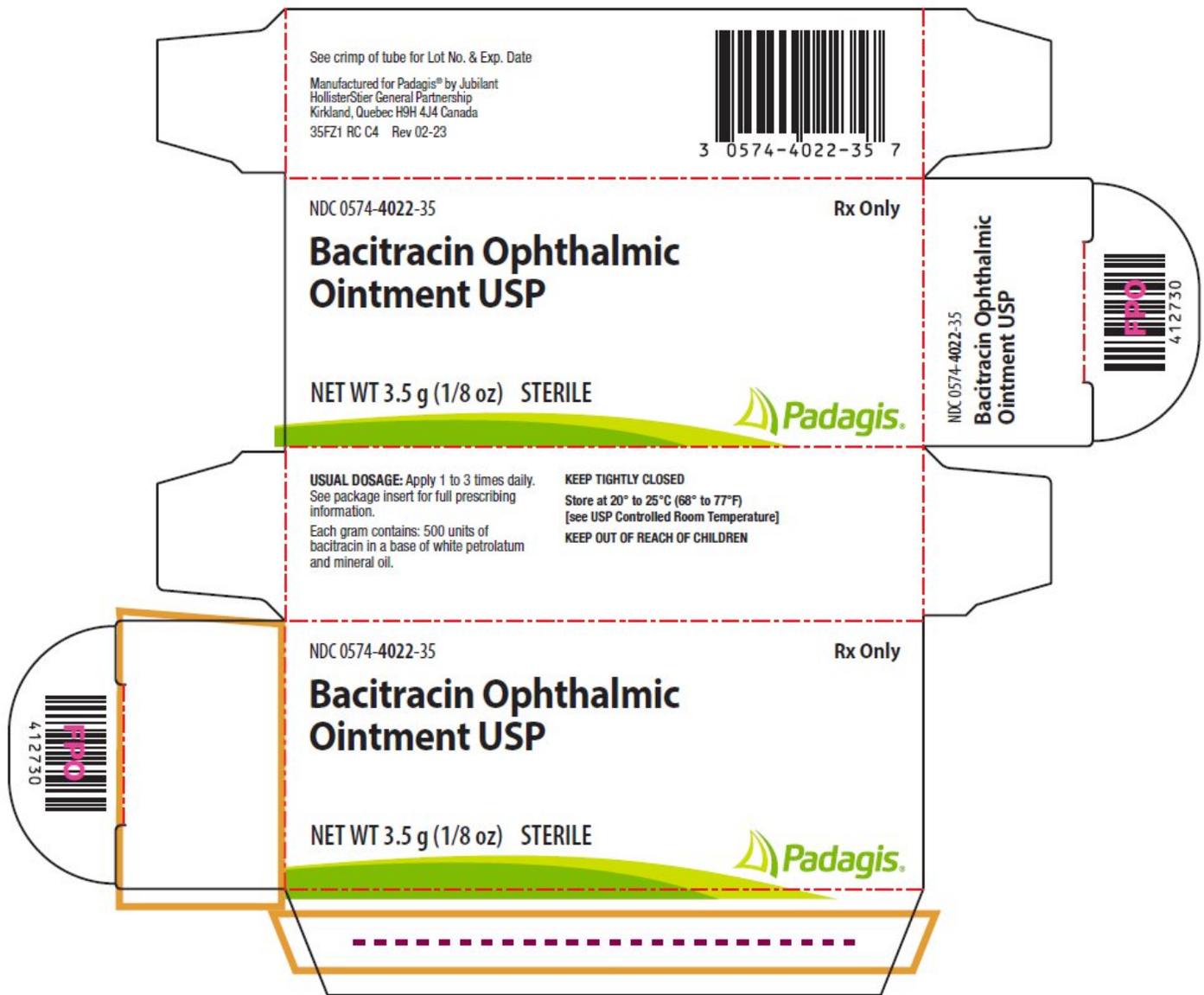
NDC 0574-4022-35

Rx Only

Bacitracin Ophthalmic Ointment USP

NET WT 3.5 g (1/8 oz)

STERILE



The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.

S/N [insert product's serial number]  
 Lot [insert product's lot number]  
 Exp [insert product's expiration date]

<b>BACITRACIN</b>			
bacitracin ointment			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0574-4022

<b>Route of Administration</b>	OPHTHALMIC
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BACITRACIN</b> (UNII: 58H6RW052I) (BACITRACIN - UNII:58H6RW052I)	BACITRACIN	500 [USP'U] in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0574-4022-01	1 in 1 CARTON	03/10/2014	09/01/2016
1	NDC:0574-4022-11	1 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0574-4022-13	3 in 1 CARTON	03/10/2014	09/01/2016
2	NDC:0574-4022-11	1 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0574-4022-35	1 in 1 CARTON	03/10/2014	
3		3.5 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA061212	03/10/2014	

**Labeler** - Padagis US LLC (967694121)

Revised: 10/2024

Padagis US LLC