

BACITRACIN - bacitracin ointment
Physicians Total Care, Inc.

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 54868-0649-1.**



Manufactured for:

Fera Pharmaceuticals, LLC

Locust Valley, NY 11560

FPBC00N

Rev. 08/09

Relabeling of "Additional Barcode Label" by:

Physicians Total Care, Inc.

Tulsa, OK 74146

PRINCIPAL DISPLAY PANEL - Carton Label

Rx only

BACITRACIN OPHTHALMIC

OINTMENT USP

STERILE

CONTAINS: 500 units of Bacitracin per gram, White Petrolatum, Mineral Oil.

NET WT 3.5 g (1/8 Oz)

USUAL DOSAGE: 3 applications daily.

See insert for complete information.

KEEP TIGHTLY CLOSED

STORE AT ROOM TEMPERATURE

KEEP OUT OF REACH OF CHILDREN

See crimp of tube for Lot No. & Exp. Date



BACITRACIN			
bacitracin ointment			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:54868-0649(NDC:48102-007-35)
Route of Administration	OPHTHALMIC		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
BACITRACIN (UNII: 58H6RWO52I) (BACITRACIN - UNII:58H6RWO52I)		BACITRACIN	500 [iU] in 1 g	
Inactive Ingredients				
Ingredient Name		Strength		
MINERAL OIL (UNII: T5L8T28FGP)				
PETROLATUM (UNII: 4T6H12BN9U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-0649-1	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	04/29/1994		

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 8/2009

Physicians Total Care, Inc.