

BACIGUENT- bacitracin ointment
Woodward Pharma Services LLC

BACIGUENT (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:

Baciguent[®] 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 Woodward Pharma Services LLC at 1-844-200-7910 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 69784-880-01 3 - 1 g sterile tamper evident tubes with ophthalmic tip.

NDC 69784-880-35 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
Woodward Pharma Services LLC
Wixom, MI 48393

Rev 11-19
5G000 CJ J1

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL - 1 g Label

Rx Only

NDC 69784-880-35

Baciguent®
(Bacitracin Ophthalmic Ointment, USP)

STERILE

NET WT 3.5 g (1/8 oz)

USUAL DOSAGE: Apply 1 to 3 times daily. See package insert for full prescribing information.

Each gram contains: 500 units of bacitracin in a base of white petrolatum and mineral oil.

KEEP TIGHTLY CLOSED

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

KEEP OUT OF REACH OF CHILDREN

BACIGUENT				
bacitracin ointment				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69784-880	
Route of Administration	OPHTHALMIC			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	BACITRACIN (UNII: 58H6RWO52I) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USP'U] in 1 g	
Inactive Ingredients				
	Ingredient Name		Strength	
	PETROLATUM (UNII: 4T6H12BN9U)			
	MINERAL OIL (UNII: T5L8T28FGP)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69784-880-01	3 in 1 CARTON	04/15/2020	
1		1 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69784-880-35	1 in 1 CARTON	04/15/2020	
2		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	04/15/2020	

Labeler - Woodward Pharma Services LLC (026749066)

