BACITRACIN- bacitracin ointment
Blossom Pharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Bacitracin Ointment

Active ingredient	**Purpose**
Bacitracin Zinc (Equal to 500 Bacitracin Units)	First Aid Antibiotic

Purpose:

First aid to help prevent infection.

Warnings:

For external use only

Dosage and Administration

Directions:

- clean the affected areas
- apply a small amount of product (an amountb equal to the surface area of the tip of the finger) on the area 1 to 3 times daily.
- may be covered with a sterile bandage

Indications and Usage

First aid to help prevent infection in:

- minor cuts
- scrapes
- burns

Stop Use and ask a doctor if:

- the condition persists or gets worse, or if a rash or other allergic reaction develops.

Do Not Use if:

- if you are allergic to any of the ingredients
- in the eyes
- over large areas of the body
- longer than 1 week unless directed by a doctor

Ask a doctor before use:

- in case of deep or puncture wounds
- animal bites
- serious burns

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away

Other information

- store at controlled room temperature 15°-30° C (59°-86° F)

Inactive ingredients

Light Mineral Oil, White Petrolatum

Principal Display Panel

Bacitracin Ointment

BP Bacitracin.jpg

BACITRACIN

bacitracin ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61767-219
Route of Administration	TOPICAL		

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:61767-219-01	28.35 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	03/06/2014	

Labeler - Blossom Pharmaceuticals (677381470)

Establishment

Name	Address	ID/FEI	Business Operations
Blossom Pharmaceuticals		677381470	manufacture(61767-219)

Revised: 3/2014 Blossom Pharmaceuticals