

BACITRACIN - bacitracin ointment
Galentic Pharma (India) Private Limited

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 500 Units	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 amount 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

Keep out of reach of children

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

Ask a doctor before use:

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

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:

Gal Bacitracin.jpg



BACITRACIN

bacitracin ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50382-005
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:50382-005-01	28.35 g in 1 TUBE		
2	NDC:50382-005-02	14.17 g in 1 TUBE		
3	NDC:50382-005-03	56.7 g in 1 TUBE		
4	NDC:50382-005-04	113.4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	08/02/2013	

Labeler - Galentic Pharma (India) Private Limited (918531450)**Establishment**

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Private Limited		918531450	manufacture(50382-005)

Revised: 8/2013

Galentic Pharma (India) Private Limited