

BACITRACIN ZINC- bacitracin zinc ointment
Anicare Pharmaceuticals Pvt. Ltd

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 Zinc Ointment

Active Ingredient

Bacitracin Zinc 500 units

Purpose

First aid antibiotic

USES

First aid to help prevent infection in

- scrapes
- minor cuts
- burns

WARNINGS

EXTERNAL USE ONLY

DO NOT USE

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

Before using, consult a doctor if you have

- deep or puncture wounds
- animal bites
- serious burns

STOP USE and ask a doctor if

- you need to use longer than 1 week
- condition persists or gets worse
- symptoms persists for more than 1 week or clear up and occur again within a few days
- a rash or other allergic reaction develops

KEEP OUT OF REACH OF CHILDREN

If swallowed get medical help or contact a Poison Control Center immediately.

DIRECTIONS

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

Other information

- Store at room temperature 15° to 25°C (59° to 77°F).
- Before using any medication, read all label directions.

Keep carton, it contains important information.

Lot No./Exp. Date: see crimp of tube.

Inactive Ingredients

Hard Paraffin, Liquid Paraffin, White Soft Paraffin

PRINCIPAL DISPLAY PANEL

Bacitracin Zinc Ointment

NET WT 0.5 OZ (14g)



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Distributed By:

Universal Distribution Center,
96 Distribution Boulevard, Edison, NJ 08817
www.universalbrandsusa.com

Lot No./ Exp. Date: see crimp of tube

Item#82697 Made in India

BACITRACIN ZINC

bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47046-158
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USP'U] in 1 g

Inactive Ingredients

Ingredient Name	Strength
PARAFFIN (UNII: I9O0E3H2ZE)	
MINERAL OIL (UNII: T5L8T28FGP)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47046-158-02	1 in 1 CARTON	12/09/2020	
1	NDC:47046-158-01	14 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
OTC monograph final	part333B	12/09/2020	

Labeler - Anicare Pharmaceuticals Pvt. Ltd (916837425)**Registrant** - Anicare Pharmaceuticals Pvt. Ltd (916837425)**Establishment**

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(47046-158)

Revised: 12/2020

Anicare Pharmaceuticals Pvt. Ltd