# 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.

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#### **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.

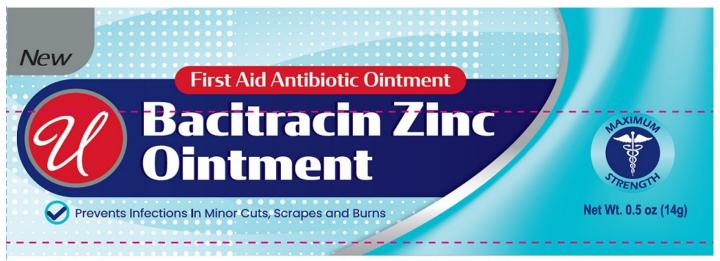
## **Inactive Ingredients**

Hard Paraffin, Liquid Paraffin, White Soft Paraffin

#### PRINCIPAL DISPLAY PANEL

#### **Bacitracin Zinc Ointment**

NET WT 0.5 OZ (14g)



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Puprose

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Universal Distribution Center, 96 Distribution Boulevard, Edison, NJ 08817

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:47046-155
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO52I)	BACITRACIN	500 [USP'U] in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E )			
MINERAL OIL (UNII: T5L8T28FGP)			
WHITE PETRO LATUM (UNII: B6E5W8RQJ4)			

1	Packaging			
#.	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47046-155-02	1 in 1 CARTON	12/09/2020	
1	NDC:47046-155-01	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(47046-155)	

Revised: 12/2020 Anicare Pharmaceuticals Pvt. Ltd