BACITRACIN ZINC- bacitracin zinc ointment STRATUS PHARMACEUTICALS INC

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

Drug Facts

Active ingredient (in each gram)

Bacitracin Zinc, USP 500 units

Purpose

First aid antibiotic

Uses

First aid to help prevent infection in

- minor cuts
- scrapes
- burns

Warnings

For external use only

Allergy alert

do not use if allergic to any of the ingredients

Do not use

- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

When using this product

do not use longer then one week unless directed by doctor

Stop use and ask a doctor if

- condition persists or gets worse
- a rash or other allergic reaction develop

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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
- May be covered with a sterile bandage

Other information

- Store at room temperature 59°F 77°F (15°C 25°C)
- Before using any medication, read all label directions. Keep carton, it contains important information.
- Do not use if seal is punctured or is not visible
- See crimp of tube and outside of carton for Lot Number and Expiration Date.
- To open, reverse cap and puncture.

Inactive Ingredient

White petrolatum

Questions or comments?

Call toll-free 1-800-442-7882

Distributed by: Stratus Pharmaceuticals Inc. 12379 SW 130th Street Miami, Florida 33186

PRINCIPAL DISPLAY PANEL - 28.35 g Tube Box

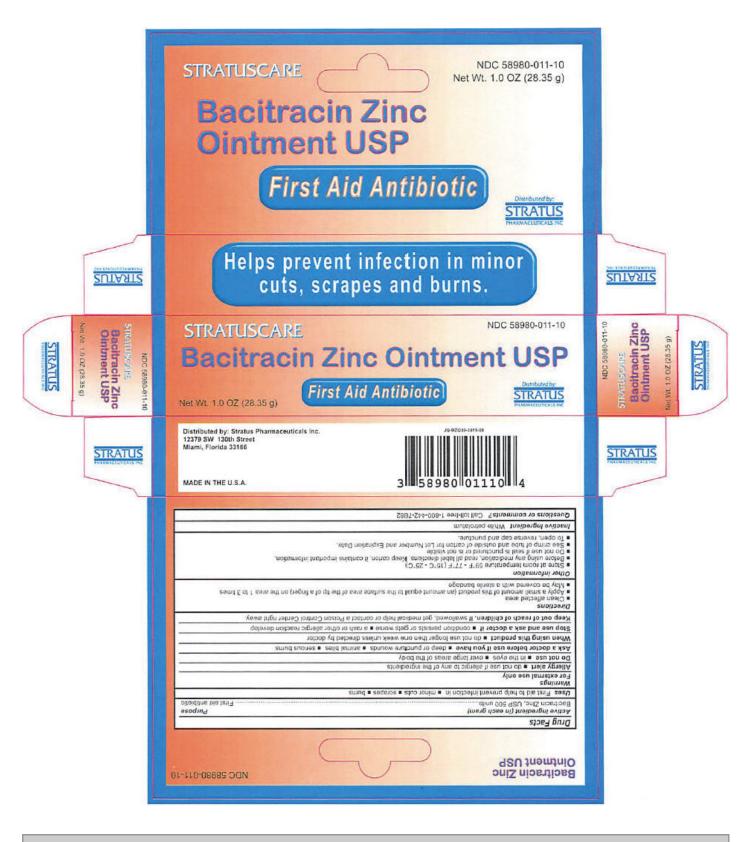
STRATUSCARE NDC 58980-011-10

Bacitracin Zinc Ointment USP

First Aid Antibiotic

Net Wt. 1.0 OZ (28.35 g)

Distributed by: STRATUS PHARMACEUTICALS INC



BACITRACIN ZINC

bacitracin zinc ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58980-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	BACITRACIN	500 [USP'U] in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
PETROLATUM (UNII: 4T6H12BN9U)		

Product Characteristics		
Color	WHITE (OFF WHITE)	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:58980-011-10	1 in 1 BOX	09/15/2017	
1	28.35 g in 1 TUBE; Type 0: Not a Combination Product		
2 NDC:58980-011-01	144 in 1 BOX	05/15/2020	
2	1 g in 1 PACKET; 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	09/15/2017	

Labeler - STRATUS PHARMACEUTICALS INC (789001641)

Establishment			
Name	Address	ID/FEI	Business Operations
TARMAC PRODUCTS INC		059890491	MANUFACTURE(58980-011), LABEL(58980-011), PACK(58980-011)

Revised: 5/2020 STRATUS PHARMACEUTICALS INC