SINGLE ANTIBIOTIC WITH BACITRACIN- bacitracin zinc ointment Dealmed Medical Supplies LLC

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.

Drug Facts

Active Ingredient (in each gram)

Bacitracin zinc (500 units bacitracin)

Purpose

First Aid Antibiotic

Uses:

First aid to help prevent infection in minor cuts, scrapes, and burns.

Warnings:

For external use only.

Keep out of reach of children.

If ingested, get medical help or contact a Poison Control Center directly.

Do Not Use:

- in the eyes or over large areas of the body, or on puncture wounds, animal bites or serious burns
- for more than 1 week unless directed by a doctor
- if allergic to any of the ingredients

Stop use, ask a doctor if:

- condition persists or gets worse
- a rash or allergic reaction develops

Directions:

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

Inactive ingredients:

mineral oil, petrolatum

Questions or Comments?

1-800-456-7077

Principal Display Panel - 0.9g Box Label

NDC 70082-601-02

dealmed

Bacitracin Ointment

First Aid to help prevent infection in minor cuts, scrapes and burns

144 Packets

NET WT. 0.9g PER PACKET



Principal Display Panel - 0.9g Pouch Label

dealmed

Bacitracin Ointment

0.9g (1/32 oz.)

Dealmed • Brooklyn, NY

www.dealmed.com



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(in each gram) Bacitracin zinc

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Uses first aid to help prevent infection in minor scrapes. cuts, and burns

Warnings

For external use only

Drug Facts (continued)

Warnings (continued)

Do not use ■ in eyes ■ over large areas of the body or on puncture wounds, animal bites or serious burns
for more than 1 week unless directed by a doctor ■ if you are allergic to any of the ingredients

Stop use and ask a doctor if ■ a rash or allergic reaction develops **condition** worsens or persists

Keep out of reach of children If ingested, contact a Poison Control Center right away.

Directions ■ clean affected area ■ apply a small amount 1 to 3 times daily ■ may cover with a sterile bandage

Inactive ingredients mineral oil, petrolatum

SINGLE ANTIBIOTIC WITH BACITRACIN

bacitracin zinc ointment

Product Information

HUMAN OTC DRUG NDC:70082-601 **Product Type** Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
bacitracin zinc (UNII: 89Y4M234ES) (bacitracin - UNII:58H6RWO52I)	bacitracin zinc	400 [USP'U] in 1 g

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

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:70082-601- 02	144 in 1 BOX	03/18/2022			
1		0.9 g in 1 POUCH; 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	03/18/2022		

Labeler - Dealmed Medical Supplies LLC (068586441)

Establishment					
Name	Address	ID/FEI	Business Operations		
Safetec of America, Inc.		874965262	MANUFACTURE(70082-601)		

Revised: 3/2022 Dealmed Medical Supplies LLC