SINGLE 0.9G TRIPLE ANTIBIOTIC- bacitracin zinc 400 units ointment Sled Distribution, 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.

Ointment

Active ingredient

(in each gram)

Bacitracin Zinc (bacitracin 400 units)

Neoycin sulfate (neoycin 3.5 mg)

Polymyxin B sulfate

(polymyxin B 5,000 units)

Purpose

Bacitracin Zinc 400 units......First aid antibiotic

Uses

First aid to help prevent infection in

- minor cuts
- scrapes
- burns

Warnings

For external use only

Do not use

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

Ask a doctor before use if

• on deep or puncture wounds, animal bites, or serious burns

Stop use and ask doctor if

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

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

Directions

- Clean the 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

Inactive ingredients

Mineral oil, Petrolatum, Purified water

Principal Display Panel

OINTMENT







Topical

















TRIPLE ANTIBIOTIC

Single 0.9 g Triple Antibiotic **Ointment**

EXPERIENCE ELEVATED FIRST AID.

NET WT. 0.9 G



Drug Facts

Active ingredients

Purpose

(in each gram)

Bacitracin zinc (bacitracin 400 units) Neomycin sulfate (neomycin 3.5 mg)

Polymyxin B sulfate (polymyxin B 5,000 units)

first aid antibiotic

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

Warnings For external use only,

Do not use ■ in eyes ■ over large areas of the body if you are allergic to any of the ingredients

longer than 1 week unless directed by a doctor.

Ask a doctor before use if you have ■ deep or puncture wounds animal bites serious burns

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Directions

- Clean the 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

Inactive Ingredients

Mineral oil, petrolatum, purified water

TO REPORT A SERIOUS ADVERSE EVENT, CONTACT +1 (866)377–8243



SLED DISTRIBUTION LLC DBA MYMEDIC 120 North Redwood Rd. Ste. A, North Salt Lake , UT 84054

MFG 20210105

EXP 20240104

LOT 20210105



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(in each gram)

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SINGLE 0.9G TRIPLE ANTIBIOTIC

bacitracin zinc 400 units ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:8 1417-108

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 ZINC	400 [USP'U] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	0.0035 g in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [USP'U] in 1 g

Inactive Ingredients	
Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETRO LATUM (UNII: 4T6 H12BN9 U)	
WATER (UNII: 059QF0KO0R)	

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:81417-108-01	1 in 1 CARTON	01/08/2021	
	1	0.9 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	01/08/2021			

Labeler - Sled Distribution, LLC (079772888)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sled Distribution, LLC		079772888	manufacture(81417-108)	

Revised: 1/2021 Sled Distribution, LLC