TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment Safetec of America, Inc.

61010-4400-2, Triple Antibiotic

Active ingredients

(in each gram)

Bacitracin Zinc (400 units Bacitracin)

Neomycin sulfate (3.5 mg Neomycin)

Polymyxin B Sulfate (Polymyxin B 5000 units)

Purpose

First aid antibiotic

Uses

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

Warnings

For external use only

Do not use

- internally
- 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 ingredient

petrolatum

Principal Display Panel - 28 g Tube Label

Safetec®

Triple Antibiotic Ointment

First Aid Infection Protection

To Help Prevent Infection in Minor Cuts, Scrapes, and Burns

Net Wt. 1 oz. (28.4g)



Triple Antibiotic Ointment

First Aid Infection Protection

To Help Prevent Infection in Minor Cuts, Scrapes, and Burns

Net Wt. 1 oz. (28.4g)

sorder No. 53207B NDC 61010-4400-2

Manufactured by Safetec of America, Inc. Buffalo, NY 14215 | 1-800-456-7077

Drug Facts

Active ingredients (in each gram) Purpose

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

Warnings For external use only

Do not use ■ internally ■ 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 ingredient petrolatum

TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61010-4400

Route of Administration TOPICAL

tem code (Source)

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I)	BACITRACIN ZINC	400 [iU] in 1 g	
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN SULFATE	5 mg in 1 g	
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII: J2VZ 07J96K)	POLYMYXIN B	5000 [iU] in 1 g	

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

	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:61010- 4400-2	28 g in 1 TUBE; Type 0: Not a Combination Product	07/25/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M004	07/25/2022	

Labeler - Safetec of America, Inc. (874965262)

Establishment				
Name	Address	ID/FEI	Business Operations	
Safetec of America, Inc.		874965262	manufacture(61010-4400)	

Revised: 2/2024 Safetec of America, Inc.