

SINGLE ANTIBIOTIC- bacitracin zinc ointment
Safetec of America, Inc.

61010-4404 Triple Antibiotic with Pain Relief

Drug Facts

Active Ingredient

Bacitracin Zinc (500 units in each gram)

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

- In the eyes or apply 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, or serious burns

Stop use and ask a doctor if the condition persists or gets worse, or if 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 (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

Hard Paraffin, Liquid Paraffin, White Soft Paraffin

Principal Display Panel - Tube Label

Safetec®

Single Antibiotic Ointment

First Aid Infection Protection with Bacitracin Zinc

Net Wt. 1 oz. (28.4g)

Reorder No. 53301

Manufactured for: Safetec of America, Inc.

Buffalo, NY 14215 | 1-800-456-7077

Made in IndiaKD/503

Safetec

Single Antibiotic Ointment

First Aid Infection Protection with Bacitracin Zinc

Net Wt. 1 oz. (28.4g)

Reorder No. 53301

Manufactured for: Safetec of America, Inc.
Buffalo, NY 14215 | 1-800-456-7077
Made in India KD/503

Drug Facts		Drug Facts (continued)	
Active Ingredient Bacitracin Zinc (500 units in each gram).....	Purpose First Aid Antibiotic	Stop use and ask a doctor if the condition persists or gets worse, or if a rash or other allergic reaction develops	
Uses First aid to help prevent infection in minor cuts, scrapes, and burns		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
Warnings For external use only		Directions Clean the affected area. Apply a small amount (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	
Do not use ■ In the eyes or apply over large areas of the body ■ If you are allergic to any of the ingredients ■ Longer than 1 week unless directed by a doctor		Other Information Store at room temperature	
Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns		Inactive Ingredients Hard Paraffin, Liquid Paraffin, White Soft Paraffin	

SINGLE ANTIBIOTIC

bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61010-4404
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [iU] in 1 g

Inactive Ingredients

Ingredient Name	Strength
PARAFFIN (UNII: I9O0E3H2ZE)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-4404-1	28.4 g in 1 TUBE; Type 0: Not a Combination Product	11/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M004	11/01/2019	

Labeler - Safetec of America, Inc. (874965262)**Establishment**

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	manufacture(61010-4404)

Revised: 2/2024

Safetec of America, Inc.