

**AMERICAN SAFETY AND FIRST AID TRIPLE ANTIBIOTIC- bacitracin zinc,
neomycin sulfate, polymyxin b sulfate ointment
Orazen 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.

American Safety & First Aid Triple Antibiotic

Active ingredients

(in each gram)

Bacitracin zinc 400 units

Neomycin sulfate equivalent to 3.5 mg of neomycin base

Polymyxin B sulfate 5,000 units

Purpose

First Aid antibiotic

First Aid antibiotic

First Aid antibiotic

Uses

first aid to help prevent infection in

- minor cuts
- scrapes
- burns

Warning

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, or serious burns

Stop use and ask a doctor if

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

Keep out of reach of children.

If swallowed contact a Poison Control Center right away.

Directions

- clean affected area
- apply small amount not more than 3 times daily
- may be covered with a sterile bandage

Inactive Ingredient

Mineral Oil, Petrolatum, Water



**American Safety
& First Aid**

Triple Antibiotic

**First Aid Antibiotic
To Help Prevent Infection**

Drug Facts

Active ingredients Purpose

(in each gram)

Bacitracin zinc First Aid
400 units.....antibiotic

Neomycin sulfate First Aid
equivalent to 3.5 mg of neomycin base.....antibiotic

Polymyxin B sulfate First Aid
5000 units.....antibiotic

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

Warnings For external use only ▶

NET WT 0.5g (1/55 OZ)

Drug Facts (continued)

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 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 ■ a rash or other allergic reaction develops

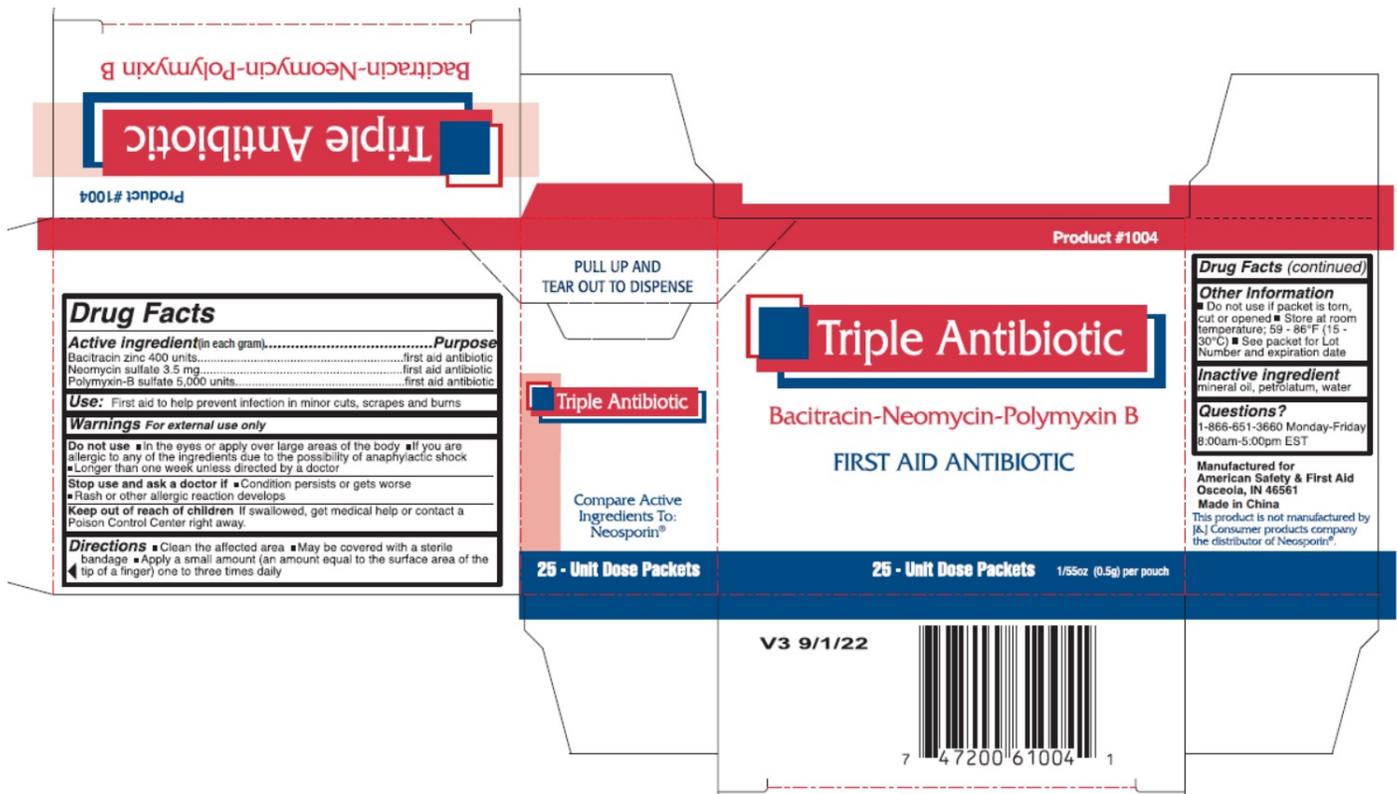
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Inactive Ingredient

Mineral Oil, Petrolatum, Water

Mfg. for American Safety & First Aid Osceola, IN 46561



AMERICAN SAFETY AND FIRST AID TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71927-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW0521)	BACITRACIN	400 [USP'U] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	0.0035 g in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ.07J96K)	POLYMYXIN B	5000 [USP'U] in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:71927-016-02	25 in 1 BOX	10/17/2022	
1	NDC:71927-016-01	0.5 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	10/17/2022	

Labeler - Orazen Inc (080916640)

Revised: 10/2022

Orazen Inc