

TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment
Provision Medical

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.

Active ingredient

(in each gram)

Bacitracin zinc (400 units bacitracin)

Neomycin sulfate (3.5 mg neomycin)

Polymyxin B sulfate (5000 units)

Purpose

First Aid Antibiotic

First Aid Antibiotic

First Aid Antibiotic

Use

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 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

petrolatum

Principal Display Panel - 0.5g Packet Label

TAMPER EVIDENT. DO NOT USE IF PACKET IS TORN OR CUT.

ointment

Helps Prevent Infection in Cuts and Scrapes

TRIPLE ANTIBIOTIC

0.5g

The **Provision** First Aid Line™

TAMPER EVIDENT. DO NOT USE IF PACKET IS TORN OR CUT.

ointment *Helps Prevent Infection in Cuts and Scrapes*

TRIPLE ANTIBIOTIC **0.5g**

Manufactured for:
Provision Medical Products
Palm Desert, CA 92211

The Provision
First Aid
Line™

Active ingredient (in each gram) **Purpose**
Bacitracin zinc (400 units bacitracin) ... First Aid Antibiotic
Neomycin sulfate (3.5 mg neomycin) First Aid Antibiotic
Polymyxin B sulfate (5000 units) First Aid Antibiotic

Use 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 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
petrolatum

EXP. LOT

TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69103-5005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
bacitracin zinc (UNII: 89Y4M234ES) (bacitracin - UNII:58H6RWO52I)	bacitracin	400 [USP'U] in 1 g
neomycin sulfate (UNII: 057Y626693) (neomycin - UNII:I16QD7X297)	neomycin	3.5 mg 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
petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69 103-5005-1	0.5 g in 1 PACKET; 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	08/29/2014	

Labeler - Provision Medical (036936831)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(69 103-5005)

Revised: 8/2014

Provision Medical