# 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.

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### **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

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#### 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.

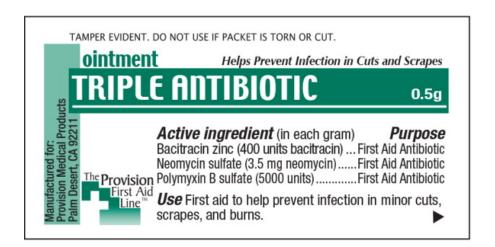
#### ointment

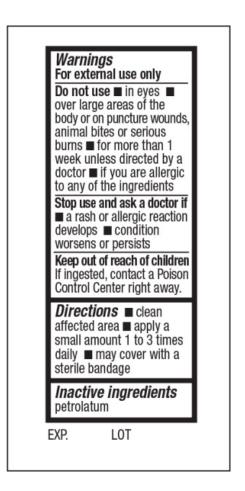
Helps Prevent Infection in Cuts and Scrapes

#### TRIPLE ANTIBIOTIC

0.5g

The **Provision** First Aid Line<sup>TM</sup>





#### 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: 89 Y4M234ES) (bacitracin - UNII:58 H6 RWO52I)	bacitracin	400 [USP'U] in 1 g
neomycin sulfate (UNII: 057Y626693) (neomycin - UNII:116QD7X297)	neomycin	3.5 mg in 1 g

polymyxin b sulfate (UNII: 19371312D4) (polymyxin b - UNII:J2VZ07J96K)	polymyxin b	5000 [USP'U] in 1 g
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Inactive Ingredients		
	Ingredient Name	Strength
petrolatum (UNII: 4T6H12BN9U)		

l	Packa	ging			
# Item Code Package Description		<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
ı	1 NDC:69103-5005-1 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(69103-5005)	

Revised: 8/2014 Provision Medical