TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment ProStat First Aid

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.

Drug Facts

Active Ingredients (each gram contains)

Bacitracin zinc 400 units

Neomycin sulfate 5 mg (equivalent to 3.5 mg of neomycin base)

Polymyxin B sulfate 5000 units

Purpose

First Aid Antibiotic

Uses

first aid to help prevent infection in:

- minor cuts
- scrapes
- 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 worsens
- 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 of this product (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 15°-25°C (59°-77°F)
- tamper evident sealed packets
- do not use packet if opened or torn

Inactive ingredients

petrolatum

Questions?

888.900.2920

prostatfa.com

PRINCIPAL DISPLAY PANEL - ProStat 25 count box

PROSTAT FIRST AID

Part No. #2009

Triple Antibiotic Bacitracin, Neomycin, Polymyxin

Ungüento Triple Antibiotico Bacitracina, neomicina, polimixina

25 pcs Unit Dose • 0.5g - (1/55 oz) each

Drug Facts

Active ingredient (each gram contains)

Uses first aid to help prevent infection in

- minor cuts
- scrapes
- 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 worsens
- a rash or other allergic reaction develops

Keep out reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Manufactured for ProStat First Aid LLC, Valencia, CA 91355



Part No. #2009

See Inside Package for Directions Ver el interior del paquete para instrucciones

Triple Antibiotic

Bacitracin, Neomycin, Polymyxin

Ungüento Triple Antibiotico

Bacitracina, neomicina, polimixina

25 pcs Unit Dose • 0.5g - (1/55 oz) each



Part No. #2009

Purpose

Triple Antibiotic

Bacitracin, Neomycin, Polymyxin

Ungüento Triple Antibiotico Bacitracina, neomicina, polimixina

25 pcs Unit Dose • 0.5g - (1/55 oz) each

Drug Facts (continued)

Directions

- clean the affected area
- apply a small amount of this product (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 15° to 25° C (59° to 77° F)
- tamper evident sealed packets
- do not use packet if opened or torn

Inactive ingredients petrolatum

Questions? 888-900-2920 prostatfa.com



PRINCIPAL DISPLAY PANEL – Front Line 25 count box FRONT LINE

Triple Antibiotic
Bacitracin, Neomycin, Polymyxin
Ungüento Triple Antibiotico
Bacitracina, neomicina, polimixina

25 pcs Unit Dose • 0.5g - (1/55 oz) each

Drug Facts

Active ingredient (each gram contains)

Purpose

Bacitracin zinc 400 units First aid antibiotic Neomycin sulfate 5 mg (equivalent to 3.5 mg of neomycin base)... First aid antibiotic Polymyxin B sulfate 5000 units First aid antibiotic

Uses first aid to help prevent infection in

- minor cuts
- scrapes
- 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 worsens
- a rash or other allergic reaction develops

Keep out reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Part No. 2009





Bacitracin, Neomycin, Polymyxin Ungüento Triple Antibiotico Bacitracina, neomicina, polimixina

See Inside Package for Directions Ver el interior del paquete para instrucciones

25 pcs Unit Dose • 0.5g - (1/55 oz) each



Triple Antibiotic

Bacitracin, Neomycin, Polymyxin Ungüento Triple Antibiotico

Bacitracina, neomicina, polimixina

25 pcs Unit Dose • 0.5g - (1/55 oz) each

Drug Facts (continued)

Directions

- clean the affected area
- apply a small amount of this product (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 15° to 25° C (59° to 77° F)
- tamper evident sealed packets
 do not use packet if opened or torn

Inactive ingredients petrolatum

Questions? 800-538-4555 www.frontlinesales.com

> Distributed by: ProStat First Aid LLC. Valencia, CA 91355

Part No. 2009

Part No. 2009

FIRST AID

Triple Antibiotic

0.5 g (1/57oz)

Distributed by: ProStat First Aid LLC, Valencia, CA 91355



0.5 g (1/57 oz.)

Distributed by:

ProStat First Aid LLC,

Valencia, CA 91355

Drug Facts

Active Ingredient Purpose

(in each gram)
Bacitracin zinc 400 units
Neomycin sulfate (3.5mg Neomycin)
Polymyxin B sulfate First Aid
5000 units......Antibiotics

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

Warnings
For external use only

Drug Facts (continued)

Warnings (continued)

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

■ 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 childrenIf 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

TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:58228-5600

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

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

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:58228-5600-1	25 in 1 BOX	09/20/2013			
1	NDC:58228-5600-0	0.5 g in 1 PACKET; Type 0: Not a Combination Product				
2	NDC:58228-5600-2	25 in 1 BOX	09/20/2013			
2	NDC:58228-5600-0	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	09/20/2013			

Labeler - ProStat First Aid (061263699)

Registrant - Safetec of America, Inc. (874965262)

Establishment				
Name	Address	ID/FEI	Business Operations	
Safetec of America, Inc.		874965262	MANUFACTURE(58228-5600)	

Revised: 9/2013 ProStat First Aid