

TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment
Acme United Corporation

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 400 units

Neomycin Sulfate 5 mg
(equivalent to 3.5 mg. of Neomycin base)

Polymyxin-B Sulfate 5000 units

Purpose

First Aid Antibiotics

Uses:

First aid to help prevent infection in:

- Minor cuts and scrapes
- Minor burns

Warnings:

For external use only. If swallowed, get medical help or contact a Poison Control Center immediately.

Keep out of the reach of children.

STOP USE AND ASK A DOCTOR IF:

- Conditions worsen or clear up and then recur
- The condition persists for more than 7 days
- A rash or allergic reaction occurs

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
- On raw surfaces, blistered areas or serious burns
- For deep lacerations or puncture wounds

WHEN USING THIS PRODUCT:

- Avoid contact with the eyes or mucus membranes

Directions:

Tamper evident packaging, do not use if packet is opened or torn.

Adults and children:

Clean the affected area, apply a small amount of this product (equal to the surface area of a fingertip) 1 to 3 times daily

Other information:

Store at room temperature

Inactive ingredients:

Petrolatum

Questions about this product: Call 1-800-835-2263 with any questions about this product.

PRINCIPAL DISPLAY PANEL – packet

NDC 0924-5603-01

Physicians CARE

**Triple Antibiotic
Ointment**

0.5 g (1/57 oz.)

Acme United Corporation

Fairfield, CT 06824 **800-835-2263**

NDC 0924-5603-01



Triple Antibiotic Ointment

0.5 g(1/57 oz.)

Acme United Corporation
Fairfield, CT 06824 800-835-2263

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
(in each gram)	
Bacitracin zinc 400 units	
Neomycin sulfate (3.5 mg Neomycin)	
Polymyxin B sulfate 5000 units	First Aid Antibiotics

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

Warnings
For external use only ▶

Drug Facts (continued)

Warnings (continued)
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 – 12 count box

PAC-KIT FIRST AID

UNIT
12-001

12 EACH

Triple Antibiotic Ointment Packets

Contains 12 ea. First Aid Antibiotic ointment packets (min. weight each, 0.5 gm) to help prevent infection in minor cuts, scrapes and burns. See back panel for Drug Facts listing.

Distributed by **Acme United Corporation** Fairfield, CT 06824 · 800-835-2263

TRIPLE ANTIBIOTIC OINTMENT PACKETS

Drug Facts

Active ingredient: (each gram contains):

Bacitracin 400 units.....First aid antibiotic
Neomycin Sulfate 5 mg.....First aid antibiotic
(equivalent to 3.5 mg. of Neomycin base)
Polymyxin-B Sulfate 5000 unitsFirst aid antibiotic

Purpose:

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
- On raw surfaces, blistered areas or serious burns
- For deep lacerations or puncture wounds

WHEN USING THIS PRODUCT:

- Avoid contact with eyes or mucous membranes

Uses

First aid to help prevent infection in:

- Minor cuts and scrapes
- Minor burns

Warnings:

For external use only. If swallowed, get medical help or contact a Poison Control Center immediately.

Keep out of the reach of children.

STOP USE AND ASK A DOCTOR IF:

- Conditions worsen or clear up and then recur
- The condition persists for more than 7 days
- A rash or allergic reaction occurs

Directions:

Tamper evident packaging, do not use if packet is opened or torn.

Adults and children:

Clean the affected area, apply a small amount of this product (equal to the surface area of a fingertip) 1 to 3 times daily

Other information: Store at room temperature.

Inactive ingredients: Petrolatum

Questions about this product: Call 1-800-835-2263 with any questions about this product.



UNIT
12-001

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TRIPLE ANTIBIOTIC OINTMENT PACKETS

Contains 12 ea. First Aid Antibiotic ointment packets (min. weight each, 0.5 gm) to help prevent infection in minor cuts, scrapes and burns. See back panel for Drug Facts listing.

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UNIQUEUSED AREA

TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-5603
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
bacitracin zinc (UNII: 89 Y4M234ES) (bacitracin zinc - UNII:89 Y4M234ES)	bacitracin zinc	400 [iU] 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 sulfate	5000 [iU] in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
petrolatum (UNII: 4T6H12BN9U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-5603-04	12 in 1 BOX		
1	NDC:0924-5603-01	0.5 g in 1 PACKET		
2	NDC:0924-5603-05	25 in 1 BOX		
2	NDC:0924-5603-01	0.5 g in 1 PACKET		
3	NDC:0924-5603-06	60 in 1 BOX		
3	NDC:0924-5603-01	0.5 g in 1 PACKET		
4	NDC:0924-5603-07	144 in 1 BOX		
4	NDC:0924-5603-01	0.5 g in 1 PACKET		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333B	03/21/2012		

Labeler - Acme United Corporation (001180207)

Registrant - Safetec of America, Inc. (874965262)

Establishment			
Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(0924-5603)