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.

First Aid Only Triple Antibiotic Ointment

Drug Facts

Active Ingredient (in each gram)

Bacitracin Zinc (400 units Bacitracin)

Neomycin Sulfate (3.5 mg Neomycin)

Polymyxin B Sulfate (Polymyxin B 5000 units)

Purpose

First Aid Antibiotic

First Aid Antibiotic

First Aid Antibiotic

Uses

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

Warnings

For external use only

Do not use:
- in the eyes
- over large areas of the body
- on puncture wounds, animal bites, or serious burns
- longer 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 the reach of children.

Directions

- Clean the affected area.
- Apply a small amount of product 1 to 3 times daily
- may be covered with a sterile bandage

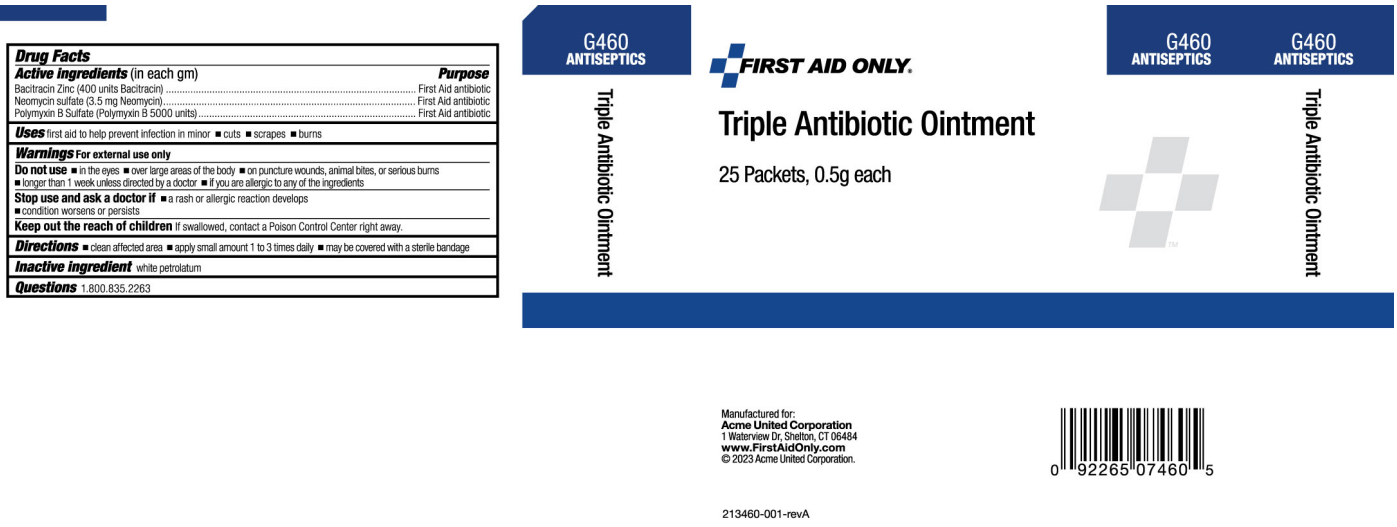
Inactive Ingredient

White Petrolatum

Questions

1-800-835-2263

Box Label



TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0924-5604(NDC:61010-5603)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	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	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:0924-5604-00	0.5 g in 1 POUCH; Type 0: Not a Combination Product	04/24/2023	
2	NDC:0924-5604-01	6 in 1 BAG	04/24/2023	
2		0.5 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:0924-5604-03	12 in 1 BOX	04/24/2023	
3		0.5 g in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:0924-5604-02	10 in 1 BOX	04/24/2023	
4		0.5 g in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:0924-5604-04	20 in 1 BOX	04/24/2023	
5		0.5 g in 1 PACKET; Type 0: Not a Combination Product		
6	NDC:0924-5604-05	25 in 1 BOX	04/24/2023	
6		0.5 g in 1 PACKET; Type 0: Not a Combination Product		
7	NDC:0924-5604-06	60 in 1 BOX	04/24/2023	
7		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	04/24/2023	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-5604) , repack(0924-5604)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-5604) , repack(0924-5604)