FIRST AID ONLY TRIPLE ANTIBIOTIC- bacitracin zinc, polymyxin b sulfate, neomycin 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

Active ingredients

Bacitracin zinc 400 units

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

Polymyxin B sulfate 5000 units

Purpose

First aid antibiotic

First aid antibiotic

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 • 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 deep lacerations or puncture wounds, animal bites, or serious burns

Stop use and ask a doctor if •condition persists or gets worse, •a rash or allergic reaction occurs, •the condition persists for more than 7 days

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

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 ingredient

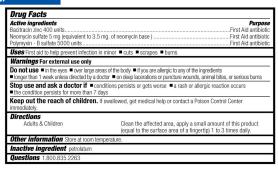
petrolatum

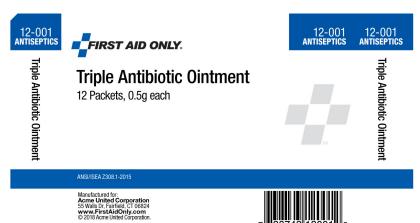
Questions or comments?

Questions 1.800.835.2263

Principal Display Panel

Carton Image





BOX12001-revG

FIRST AID ONLY TRIPLE ANTIBIOTIC

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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-5605	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	BACITRACIN	417.8 [iU] in 1 g			
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5322.8 [iU] in 1 g			
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	3.5 mg in 1 g			

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0924-5605-07	144 in 1 BOX, UNIT-DOSE	11/12/20 19		
1		0.5 g in 1 PACKET; Type 0: Not a Combination Product			
2	NDC:0924-5605-05	25 in 1 BOX, UNIT-DOSE	11/12/20 19		
2		0.5 g in 1 PACKET; Type 0: Not a Combination Product			

3 NDC:0924-5605-06	60 in 1 CARTON	11/12/20 19	
3	0.5 g in 1 PACKET; Type 0: Not a Combination Product		
4 NDC:0924-5605-04	12 in 1 CARTON	11/12/20 19	
4	0.5 g in 1 PACKET; Type 0: Not a Combination Product		
5 NDC:0924-5605-03	10 in 1 CARTON	11/12/2019	
5	0.5 g in 1 PACKET; Type 0: Not a Combination Product		
6 NDC:0924-5605-01	0.5 g in 1 PACKET; Type 0: Not a Combination Product	11/12/20 19	
7 NDC:0924-5605-02	6 in 1 BAG	11/12/2019	
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	11/12/2019		

Labeler - Acme united Corporation (001180207)

Establishment			
Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-5605), repack(0924-5605)

Establishment			
Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-5605), repack(0924-5605)

Establishment			
Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0924-5605)

Revised: 11/2019 Acme united Corporation