

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

Drug Facts	
Active ingredients	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 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 conditions persists or gets worse a rash or allergic reaction occurs the condition persists for more than 7 days	
Keep out the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
Directions	
Adults & 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 1.800.835.2263	

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ANTISEPTICS



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Triple Antibiotic Ointment

Triple Antibiotic Ointment
12 Packets, 0.5g each



Triple Antibiotic Ointment

ANSI/ISEA Z308.1-2015

Manufactured for:
Acme United Corporation
55 Walls Dr, Fairfield, CT 06424
www.FirstAidOnly.com
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FIRST AID ONLY TRIPLE ANTIBIOTIC

bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment

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: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	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:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-5605-07	144 in 1 BOX, UNIT-DOSE	11/12/2019	
1		0.5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0924-5605-05	25 in 1 BOX, UNIT-DOSE	11/12/2019	
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	11/12/20 19	
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	11/12/20 19	
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	11/12/20 19	

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