TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, and 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

• ACTIVE INGREDIENT

Bacitracin zinc 400 units

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

Polymyxin - B sulfate 5000 units

Active ingredient (in each gram)	Purpose
Bacitracin Zinc 400 Units	First Aid Antibiotic
Neomycin Sulfate 5mg (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

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

•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 and Children Clean the affected area. Apply a small amount of product

(equal to the surface area of a fingertip) 1 to 3 times daily. May be covered with a sterile bandage.

OTHER INFORMATION

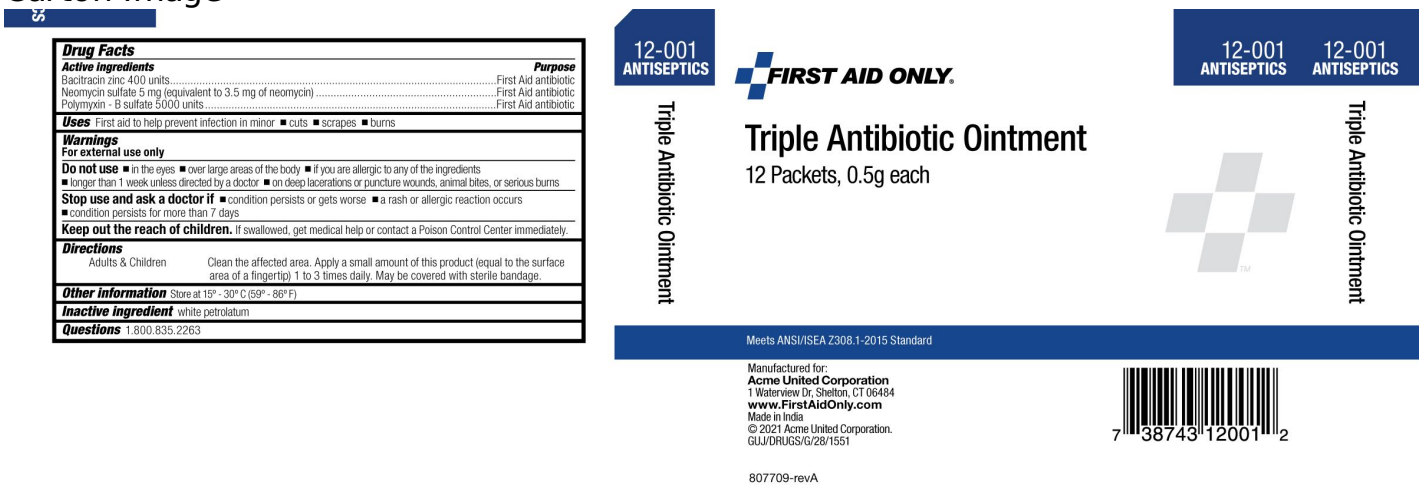
Store at 15°- 30°C (59°- 86°F)

INACTIVE INGREDIENT

White Petrolatum

Questions 1.800.835.2263

Carton Image



TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, and polymyxin b sulfate ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0924-5610(NDC:50382-023)
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 SULFATE	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:0924-5610-02	25 in 1 CARTON	08/05/2022	
1		0.5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0924-5610-00	0.5 g in 1 PACKET; Type 0: Not a Combination Product	08/05/2022	
3	NDC:0924-5610-01	12 in 1 CARTON	08/05/2022	
3		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	08/04/2022	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	repack(0924-5610) , relabel(0924-5610)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	repack(0924-5610) , relabel(0924-5610)

Revised: 8/2022 Acme United Corporation