FIRST AID ONLY 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 Ingredients (in each gram)

Bacitracin zinc 400 units

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

Polymyxin B sulfate 5000 units

Purpose

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 reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- clean the affected area
- apply small amount 1 to 3 times daily
- may be covered with a sterile bandage

Other Information

Store at room temperature

Inactive Ingredient

white petrolatum

Questions

1.800.835.2263

Box Label

FIRST AID ONLY TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-5618(NDC:61040-226)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 U in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 U in 1 g

Inactive Ingredients

Ingredient Name	Strength
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-5618-04	60 in 1 BOX	02/24/2023	
1		0.5 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0924-5618-00	0.5 g in 1 POUCH; Type 0: Not a Combination Product	02/24/2023	
3	NDC:0924-5618-02	12 in 1 BOX	06/12/2023	
3		0.5 g in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:0924-5618-03	25 in 1 BOX	06/12/2023	
4		0.5 g in 1 POUCH; 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	02/24/2023	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-5618) , repack(0924-5618)

Revised: 6/2023   Acme United Corporation