FIRST AID ANTIBIOTIC PLUS BURN RELIEFbacitracinzinc,neomycinsulfate,polymxinbsulfate,pramoxinehci ointment Trifecta Pharmaceuticals USA LLC

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.

Globe First Aid Antibiotic Plus Burn Relief

Active Ingredient

Pramoxine HCI

Purpose Section

External Analgesic

Active Ingredient

Polymyxin B Sulfate

Purpose

First Aid Antibiotic

Active Ingredient

Bacitracin Zinc

Purpose

First Aid Antibiotic

Neomycin Sulfate

Purpose

First Aid Antibiotic

Uses

First Aid to help prevent infection and for the temporary relief of pain or discomfort in minor cuts, scrapes and 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

Ask Doctor before use if you have

- Deep or puncture wounds
- Animal Bites
- Serious Burns

Stop Use and ask a doctor if

- Condition persists or gets worse
- You need to use longer than 1 week
- A rash or other allergic reaction develops
- symptoms persist for more than 1 week or clear up and occur again within a few days

Directions

Adults and children 2 years of age and older:

- Clean the affected area and dry thoroughly.
- Apply a small amount of this product, an mount equal to the surgace area of the tip of a finger) on the area 1 to 3 times daily
- May be covered with a sterile bandage

Children under 2 years old: ask a doctor

Inactive Ingredients

White Petrolatum

Questions

Call 1-888-296-9067

Storage Information

- Store at 20° to 25°C (68° to 77°F).
- See carton or tube crimp for lot number and expiration date

Keep out of reach of children

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

Other Information

Distributed By:

Trifecta Pharmaceuticals USA®

101 NE Third Avenue, Suite 1500

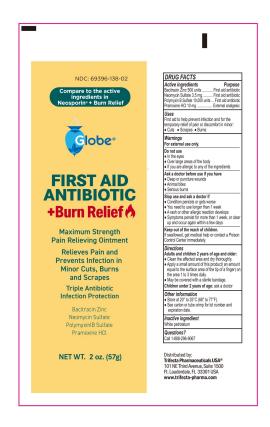
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INNER TUBE



FIRST AID ANTIBIOTIC PLUS BURN RELIEF

bacitracinzinc, neomycinsulfate, polymxinbsulfate, pramoxinehci ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-138
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g	
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII: J2VZ 07J96K)	POLYMYXIN B	10000 [USP'U] in 1 g	
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	3.5 mg in 1 g	

BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052	I) BACITRACIN	500 [USP'U] in 1 g
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Inactive Ingredients		
Ingredient Name	Strength	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-138- 02	1 in 1 BOX	09/04/2023	
1		57 g in 1 TUBE; 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	09/04/2023	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 9/2023 Trifecta Pharmaceuticals USA LLC