TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, polymyxin b sulfate. 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.

Urgent Triple Antibiotic Ointment

Active ingredients (each gram contains)

Bacitracin zinc 400 units Neomycin sulfate 3.5 mg Polymyxin B sulfate 5,000 units

Purpose

First aid antibiotic

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

Uses first aid to help prevent infection in minor: ● cuts ● scrapes ● burns

Warnings

For external use only.

Ask Doctor Before Use

Ask Doctor before use if you have deep or puncture wounds, animal bites, or serious burns.

Do Not Use

- In the eyes
- Over large areas of the body
- If you are allergic to any of the ingredients

Stop Use and ask a doctor

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

Directions

- clean the affected area and dry thoroughly.
- apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- may be covered with a sterile bandage.

Inactive ingredient light Mineral Oil, White Petrolatum

Other information

• store at 20° to 25°C (68° to 77°F)

Questions? Call 1-760-642-2638

Manufactured For

Manufactured for

Urgent First Aid®

2603 Industry Street

Oceanside, CA 92054

www.urgentfirstaid.com

OUTSIDE BOX



INNER PACKET



TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate. ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I)	BACITRACIN	400 [USP'U] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII: J2VZ 07J96K)	POLYMYXIN B	5000 [USP'U] in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
WHITE PETROLATUM (UNII: B6E5W8RQJ4)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:69396-125- 05	25 in 1 BOX	07/23/2023	
1	0.5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing In	Marketing Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	07/18/2023	

Labeler - TRIFECTA PHARMACEUTICALS USA LLC (079424163)

Registrant - Trifecta Pharmaceuticals USA (079424163)

Revised: 7/2023 TRIFECTA PHARMACEUTICALS USA LLC