TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, polymyxin b sulfate. ointment TRIFECTA PHARMACEUTICALS USA LLC

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.

Do not use ● in the eyes

- over large areas of the body
- if you are allergic to any of the ingredients.

Ask a 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

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

- To open: unscrew cap, pull tab to remove foil seal
- store at 20° to 25°C (68° to 77°F)
- see carton or tube for lot number and expiration date.

Questions? Call 1-888-296-9067

Distributed by:

Trifecta Pharmaceuticals USA™ 101 NE Third Avenue, Suite 1500 Ft. Lauderdale, FL 33301, USA 1-888-296-9067

Packaging





TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate. ointment

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-002	
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)			
PETROLATUM (UNII: 4T6H12BN9U)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69396-002- 20	1 in 1 BOX	03/13/2017		
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:69396-002- 05	1 in 1 BOX	08/23/2016		
2		15 g in 1 TUBE; Type 0: Not a Combination Product			
3	NDC:69396-002- 09	144 in 1 BOX	03/09/2022		
3		0.9 g in 1 PACKET; Type 0: Not a Combination Product			
4	NDC:69396-002- 25	25 in 1 BOX	03/14/2023		
4		0.9 g in 1 PACKET; Type 0: Not a Combination Product			
5	NDC:69396-002- 22	1 in 1 BOX	02/01/2022		
5		57 g in 1 TUBE; Type 0: Not a Combination Product			
6	NDC:69396-002- 23	2 in 1 BOX	02/29/2024		
6		28.4 g in 1 TUBE; Type 0: Not a Combination Product			
7	NDC:69396-002- 44	4 in 1 BOX	02/29/2024		
7		28.4 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 Drug	M004	03/10/2015		

Labeler - TRIFECTA PHARMACEUTICALS USA LLC (079424163)

Registrant - Trifecta Pharmaceuticals USA (079424163)

Revised: 2/2024 TRIFECTA PHARMACEUTICALS USA LLC