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.

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

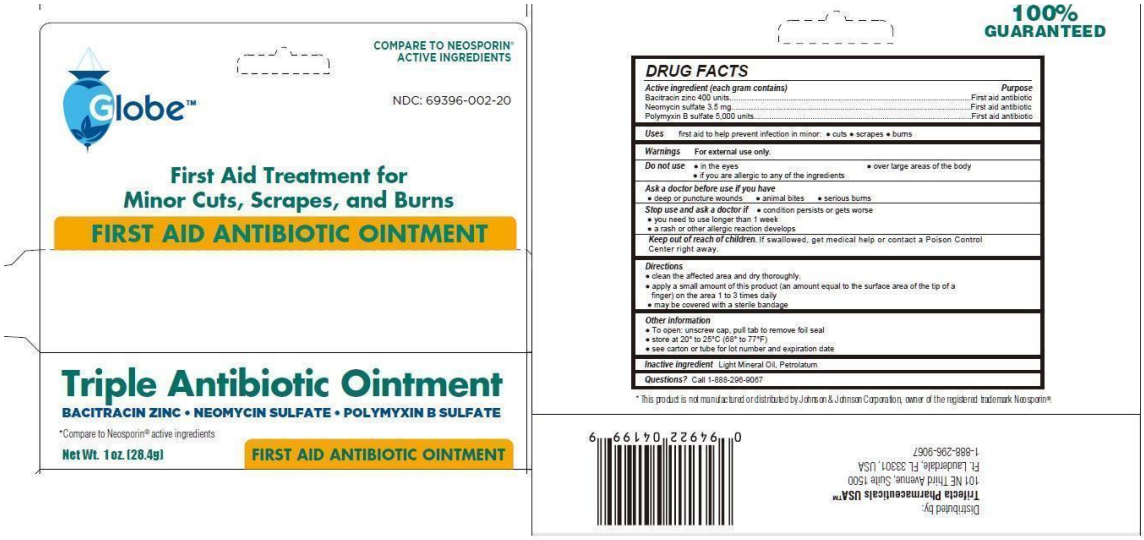
● To open: unscrew cap, pull tab to remove foil seal
● store at 20° to 25°C (68° to 77°F)

● 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

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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:58H6RWO52I)	BACITRACIN	400 [USP'U] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [USP'U] in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**

LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	03/10/2015	

Labeler - TRIFECTA PHARMACEUTICALS USA LLC (079424163)

Registrant - Trifecta Pharmaceuticals USA (079424163)

Revised: 3/2023 TRIFECTA PHARMACEUTICALS USA LLC