# 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.

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# **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.

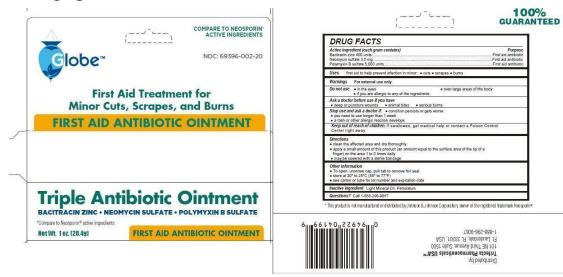
**Questions?** Call 1-888-296-9067

Distributed by:

Trifecta Pharmaceuticals USATM

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# **Packaging**



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<b>Product Information</b>	roduct Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-002			
Route of Administration	TOPICAL					

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	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)			

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
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			

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: 5/2018 TRIFECTA PHARMACEUTICALS USA LLC