

TRIBIOTIC- bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment
HART Health

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.

TRIBIOTIC

Active Ingredients (in each gram)

Bacitracin Zinc 400 units

Neomycin Sulfate 5 mg (equivalent to 3.5mg neomycin base)

Polymyxin B Sulfate 5,000 units

Purpose:

Topical Antibiotic

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Uses: First aid to help prevent infection and temporarily relieve pain in

- minor cuts
- scrapes
- burns
- abrasions

Warnings: For external use only

Serious burns require immediate medical attention

Allergy alert: Do not use if you are allergic to any of the ingredients

do not use

- in or near the eyes
- over large portions of the body
- longer than 7 days unless directed by a doctor
- more than 1 to 3 times daily

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition worsens or lasts for more than 7 days
- a rash or other allergic reaction occurs

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

Directions:

Do not use more than directed.

Adults and children 12 years of age and over:

- clean the affected area
- apply 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

Children under 12 years of age: ask a doctor

Petrolatum





TRIBIOTIC

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50332-0032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6RWO52I)	BACITRACIN	400 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:H6QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0032-6	10 in 1 BOX, UNIT-DOSE	10/03/2005	
1		.5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0032-3	25 in 1 BOX, UNIT-DOSE	10/03/2005	
2		.5 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:50332-0032-5	144 in 1 BOX, UNIT-DOSE	10/03/2005	
3		.5 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:50332-0032-1	10 in 1 BOX, UNIT-DOSE	10/03/2005	
4		.9 g in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:50332-0032-2	25 in 1 BOX, UNIT-DOSE	10/03/2005	
5		.9 g in 1 PACKET; Type 0: Not a Combination Product		
6	NDC:50332-0032-4	144 in 1 BOX, UNIT-DOSE	10/03/2005	
6		.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	10/03/2005	

Labeler - HART Health (069560969)

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HART Health