TRIPLE ANTIBIOTIC - bacitracin zinc, neomycin sulfate, polymyxin b ointment Kareway Product, Inc.

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.

Drug Facts

Active ingredient

Bacitracin Zinc 400 units

Neomycin Sulfate 3.5mg

Polymyxin B Sulfate 5,000 units

Purpose

First aid antibiotic

First aid antibiotic

First aid antibiotic

Uses

First aid to help prevent infection in minor:

- cuts
- scrapes
- burns

Warnings

For external use only

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

Ask a doctor before use if you have

- serious burns
- deep or puncture wounds
- animal bites

When using this product

- do not use in the eyes
- do not apply over large areas of the body

Stop use and ask a doctor if

- you need to use more than 1 week
- condition persists or gets worse
- symptoms persist for more than 1 week or clear up and occur again within a few days.
- rash or other allergic reaction develops

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 years of age or older:
- clean the affected area
 - apply a small amount of this product (an amount equal tot the surface area of the tip of a finer) on the area 1 to 3 times daily
 - may be covered with a sterile bandage
- children under 2 years of age: ask a doctor

Other information

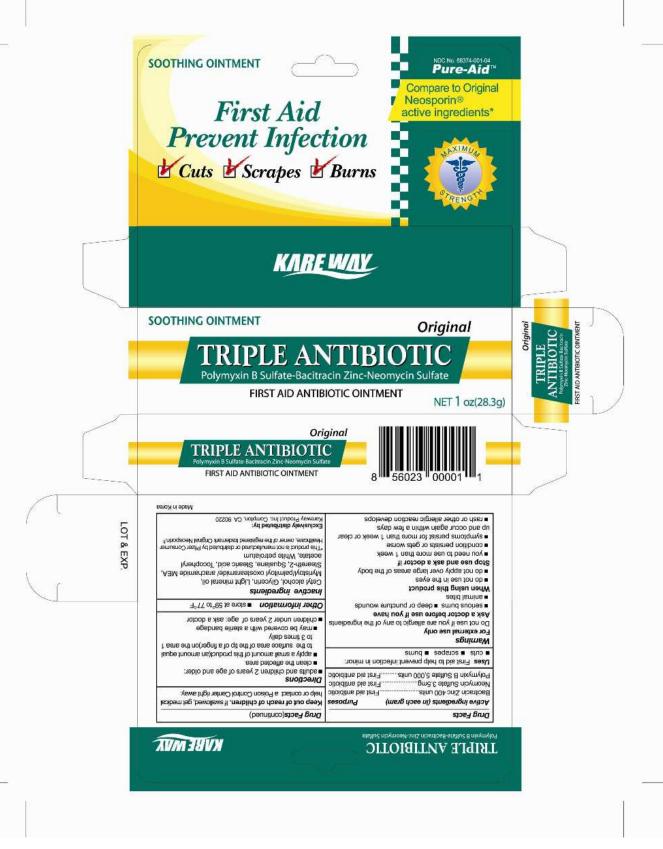
• store at 59° to 77°F

Inactive ingredients

Cetyl alcohol, Glycerin, Light mineral oil, Myristoyl/palmitoyl oxostearamide/ arachamide MEA, Steareth-w, Squalane, Stearic acid, Tocopheryl acetate, White petrolatum

Package label panel

Triple Antibiotic Ointment



TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	BACITRACIN ZINC	400 [USP'U] in 1 g		
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g		
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B SULFATE	5000 [USP'U] in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
CETYL ALCOHOL (UNII: 936JST6JCN)			
GLYCERIN (UNII: PDC6A3C0OX)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
STEARETH-2 (UNII: V56DFE46J5)			
SQUALANE (UNII: GW89575KF9)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
.ALPHATO COPHERO L ACETATE, D- (UNII: A7E6112E4N)			
PETROLATUM (UNII: 4T6H12BN9U)			

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:67510-0070-1	1 in 1 BOX				
1	28 g in 1 TUBE				
2 NDC:67510-0070-5	1 in 1 BOX				
2	14 g in 1 TUBE				
3 NDC:67510-0070-3	1 in 1 BOX				
3	9.4 g in 1 TUBE				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333B	08/10/2011			

Labeler - Kareway Product, Inc. (121840057)

Revised: 8/2011 Kareway Product, Inc.