PENTREXCILINA TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, polymyxin b ointment OPMX 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.

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
- in the eyes
- over large areas of body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

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
 - o 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

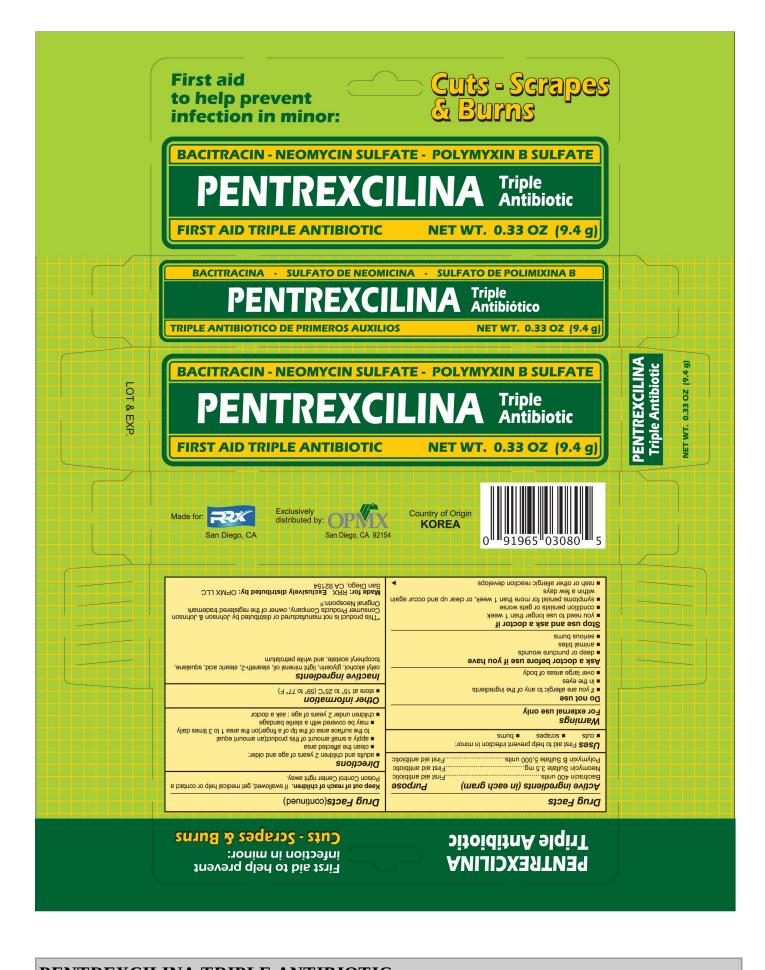
• store at 15° - 25° C (59° to 77°F)

Inactive ingredients

Cetyl alcohol, Glycerin, Light mineral oil, Squalane, Steareth-2, Stearic acid, Tocopheryl acetate, dand White petrolatum

Package label panel

Pentrexcilina Triple Antibiotic



PENTREXCILINA TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b ointment

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-080	
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	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	
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)		

I	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69729-080-33	1 in 1 BOX			
1		9.4 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 final	part333B	08/01/2012		

Labeler - OPMX LLC (029918743)

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