TRIPLE ANTIBIOTIC- bacitracin zinc neomycin sulfate polymyxin b sulfate ointment Preferred Pharmaceuticals, 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.

Bacitracin Zinc, Neomycin Sulfate, Polymyxin B Sulfate Ointment

ACTIVE INGREDIENTS

(in each gram)

Bacitracin zinc, USP 400 units Neomycin sulfate, USP 3.5 mg Polymyxin B sulfate, USP 5,000 units

PURPOSE

First aid antibiotic

USES

Helps prevent infection in

- minor cuts
- scrapes
- burns

WARNINGS

For external use only

Allergy alert:

• do not use if allergic to any of the ingredients

DO NOT USE

- in the eyes
- over large areas of the body

ASK A DOCTOR BEFORE USE IF YOU HAVE

- deep or puncture wounds
- animal bites
- serious burns

WHEN USING THIS PRODUCT

• do not use longer than 1 week unless directed by a doctor

STOP USE AND ASK A DOCTOR IF

- condition persists or gets worse
- a 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

- clean affected area
- apply a small 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

Other Information

- Store at controlled room temperature 59° 86°F (15° 30°C).
- Protect from freezing.

INACTIVE INGREDIENT

White petrolatum

HOW SUPPLIED

Triple Antibiotic Ointment comes in 28gr tubes

NDC - 68788-9811-2

QUESTIONS?

1-800-432-8534 between 9 am and 4 pm EST, Monday – Friday.

Relabeled By Preferred Pharmaceuticals, Inc

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



TRIPLE ANTIBIOTIC

bacitracin zinc neomycin sulfate polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-9811(NDC:0472-0179)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO52I)	BACITRACIN ZINC	400 [iU] 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 [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:68788-9811-2	28 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	04/25/2012	

Labeler - Preferred Pharmaceuticals, Inc (791119022)

Establishment			
Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc		791119022	RELABEL(68788-9811)

Revised: 4/2012 Preferred Pharmaceuticals, Inc