TRIPLE ANTIBIOTIC- triple antibiotic ointment B8 Sales, 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.

PIO Put it on®

Triple Antibiotic OintmentTM

First Aid to Help Prevent Infection In Minor Cuts, Scrapes, and Burns

25 Packets

Each Packet Net.Wt.0.9gm

Drug Facts

Active ingredients (in each gram)

Bacitradn Zinc (400 units Bacitracin)

Neomycin Sulfate 5 mg

(equivalent to 3.5 mg Neomycin base)

Polymyxin-B Sulfate 5000 units

Purpose

First aid antibiotic

Uses

First aid to help prevent infection in minor cuts, scrapes and burns

Warnings

For external use only

Do not use

- in the eyes
- internally
- over large areas of the body
- if you are allergic to any of the ingredients
- longer than 1 week unless directed by a doctor

Stop use and ask a doctor If

- the condition persists or gets worse
- a rash or other allergic reaction develops

Keep out reach of children. If swallowed, get

medical help or contact a Poison Control Center right away.

Directions

Adults and children 2 years and over:

- clean the affected area
- 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 dally
- may be covered with a sterile bandage

Children under 2 years:

consult a doctor

Other information

- store at room temperature (do not freeze)
- do not use any opened or torn packets

Inactive ingredients

petrolatum

Triple Antibiotic OintmentTM

Manufactured for:

B8 SALES

Cincinnati,0hio 4521S

888-826-6208

www.b8sales.com

PIO Put it on®

Principal Display Panel

Triple Antibiotic Ointment – Carton Label

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TRIPLE ANTIBIOTIC

triple antibiotic ointment

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:50607-5600

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Bacitracin Zinc (UNII: 89 Y4M234ES) (Bacitracin Zinc - UNII:89 Y4M234ES) Bacitracin Zinc (UNII: 057Y626693) (Neomycin - UNII:116 QD7X297) Bacitracin Zinc (UNII: 057Y626693) (Neomycin - UNII:116 QD7X297) Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K) Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)

| l | Inactive Ingredients | |
|---|-------------------------------|----------|
| l | Ingredient Name | Strength |
| ı | petrolatum (UNII: 4T6H12BN9U) | |

| Product Characteristics | | | |
|-------------------------|---------------|--------------|--|
| Color | white (white) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |

Contains

| P | Packaging | | | | | | |
|---|------------------|---------------------|----------------------|--------------------|--|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | | |
| 1 | NDC:50607-5600-1 | 25 in 1 BOX | | | | | |
| 1 | | .9 g in 1 POUCH | | | | | |
| 2 | NDC:50607-5600-2 | 144 in 1 BOX | | | | | |
| 2 | | .9 g in 1 POUCH | | | | | |

| Marketing Information | | | | | | |
|-----------------------|--|----------------------|--------------------|--|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | |
| OTC monograph final | part333 | 05/01/2010 | | | | |
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Labeler - B8 Sales, Inc. (833208635)

Revised: 4/2010 B8 Sales, Inc.