

POLY BACITRACIN- bacitracin zinc and polymyxin b sulfate ointment
Phoenix Global Supply Group, 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.

Poly Bacitracin

Drug Facts

| <i>Active ingredients (each gram contains)</i> | <i>Purpose</i> |
|---|-----------------------|
| Bacitracin zinc 500 units | First aid antibiotic |
| Polymyxin B sulfate 10,000 units | First aid antibiotic |

Uses

first aid to help prevent infection in minor:

- cuts
- scrapes
- burns

Warnings

For external use only

Do not use

- in the eyes
- over large areas of the body
- if you are allergic to any of the ingredients

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition persists or gets worse
- you need to use longer than 1 week
- 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 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 daily
- may be covered with a sterile bandage

Other information

- To open: unscrew cap, pull tab to remove foil seal.

- store at 20°-25°C (68°-77°F)
- See carton or tube crimp for lot number and expiration date.

Inactive ingredient

white petrolatum

Questions?

Call **1-877-745-6888**

Distributed by:
Phoenix Global Supply Group, Inc.
White Plains, NY 10604

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

Poly Bacitracin

Bacitracin Zinc • Polymyxin B Sulfate

First Aid Antibiotic Ointment

NDC 52426-420-06

NET WT 1 oz (28.4 g)

Compare to the active ingredients in POLYSPORIN®*

HELPS PREVENT INFECTION
of MINOR CUTS, SCRAPES, AND BURNS

First Aid Antibiotic Ointment

Poly Bacitracin

Bacitracin Zinc • Polymyxin B Sulfate

First Aid Antibiotic Ointment

CNS001-1-0
0810-0

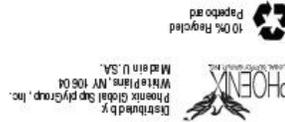
NDC 52426-420-06

Poly Bacitracin

Bacitracin Zinc • Polymyxin B Sulfate

First Aid Antibiotic Ointment

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Drug Facts (continued)

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Inactive ingredient
White petrolatum

Questions?
Call 1-8-77-45-6888
*This product is not manufactured or distributed by Monarch Pharmaceuticals, Inc., owner of the registered trademark Polypharm®.

POLY BACITRACIN

bacitracin zinc and polymyxin b sulfate ointment

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52426-420 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------|-------------------|
| Bacitracin zinc (UNII: 89Y4M234ES) (Bacitracin zinc - UNII:89Y4M234ES) | Bacitracin zinc | 500 [iU] in 1 g |
| Polymyxin B sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K) | Polymyxin B sulfate | 10000 [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:52426-420-05 | 1 in 1 CARTON | | |
| 1 | | 14.2 g in 1 TUBE | | |
| 2 | NDC:52426-420-06 | 1 in 1 CARTON | | |
| 2 | | 28.4 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part333B | 09/23/2010 | |

Labeler - Phoenix Global Supply Group, Inc (843189908)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|---------------------|
| Axellia Pharmaceuticals AS | | 561816174 | MANUFACTURE |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Axellia Pharmaceuticals ApS | | 305814345 | MANUFACTURE |

Revised: 9/2010

Phoenix Global Supply Group, Inc