TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, and polymyxin b sulfate ointment Proficient Rx LP

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.

Triple Antibiotic Ointment

Drug Facts

Active ingredients (in each gram)

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

Purpose

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 the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- you need to use longer than one week
- condition persists or gets worse
- rash or other allergic reaction develops

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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

- store at 15°-30°C (59°-86°F). Protect from freezing.
- before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredient

white petrolatum

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Distributed by: H2-Pharma, LLC

Montgomery, AL 36117

Relabeled by: **Proficient Rx LP** Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

NDC 71205-600-28 *Compare to the active ingredients in Neosporin® Original Ointment

Triple Antibiotic Ointment

Bacitracin zinc | Neomycin sulfate | Polymyxin B sulfate Ointment First aid antibiotic

For external use only

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

Net wt. 1 oz (28 g)





NDC 71205-600-28

Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320

Triple Antibiotic 1 oz (28 g) Ointment Lot #00000 NDC 71205-600-28

SN# MASTER Exp:00/00/00

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SN#MASTER Exp:00/00/00



GTIN: 00371205600280 SN# MASTER Exp. 00/00/00 Lot #:00000

Triple Antibiotic

1 oz (28 g) Ointment

Each gram contains: Bacitracin zinc USP, 400 units / Neomycin 3.5 mg / Polymyxin B sulfate USP, 5,000 units First aid antibiotic

See package

For external use only

Product ID: ST060028

Dist. By: H2-Pharma, LLC Montgomery, AL 36117 Store at 15°-30°C (59°-86°F). Protect from freezing.

Keep medication out of the reach of children

TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, and polymyxin b sulfate ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71205-600(NDC:61269-179)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------|------------------------|
| BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I) | 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: J2VZ 07J96K) | POLYMYXIN B | 5000 [USP'U] in 1 g |

Inactive Ingredients Ingredient Name Strength WHITE PETROLATUM (UNII: B6E5W8RQJ4)

| Product Characteristics | | |
|-------------------------|-----------------------|--------------|
| Color | YELLOW (light yellow) | Score |
| Shape | | Size |
| Flavor | | Imprint Code |
| Contains | | |

| Packaging | | | | |
|-----------|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:71205-600- 28 | 1 in 1 CARTON | 08/18/2021 | |
| 1 | | 28 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 | 05/24/2021 | |
| | | | |

Labeler - Proficient Rx LP (079196022)

| Establishment | | | | |
|------------------|---------|-----------|---------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Proficient Rx LP | | 079196022 | RELABEL(71205-600) | |

Revised: 8/2021 Proficient Rx LP