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

Taro Pharmaceuticals U.S.A., Inc.

Triple Antibiotic

Drug Facts

| Active ingredients (in each gram) | Purpose |
|-------------------------------------|----------------------|
| Bacitracin zinc USP 400 units | First aid antibiotic |
| Neomycin sulfate USP 3.5 mg | First aid antibiotic |
| Polymyxin B sulfate USP 5,000 units | First aid antibiotic |

Uses

first aid to help prevent infection in minor:

- cuts
- scrapes
- burns

Warnings

For external use only.

Do not use

- 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 1 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 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° to 25°C (68° to 77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

cocoa butter, cottonseed oil, olive oil, sodium pyruvate, vitamin E, white petrolatum

Questions?

Call **1-866-923-4914**

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

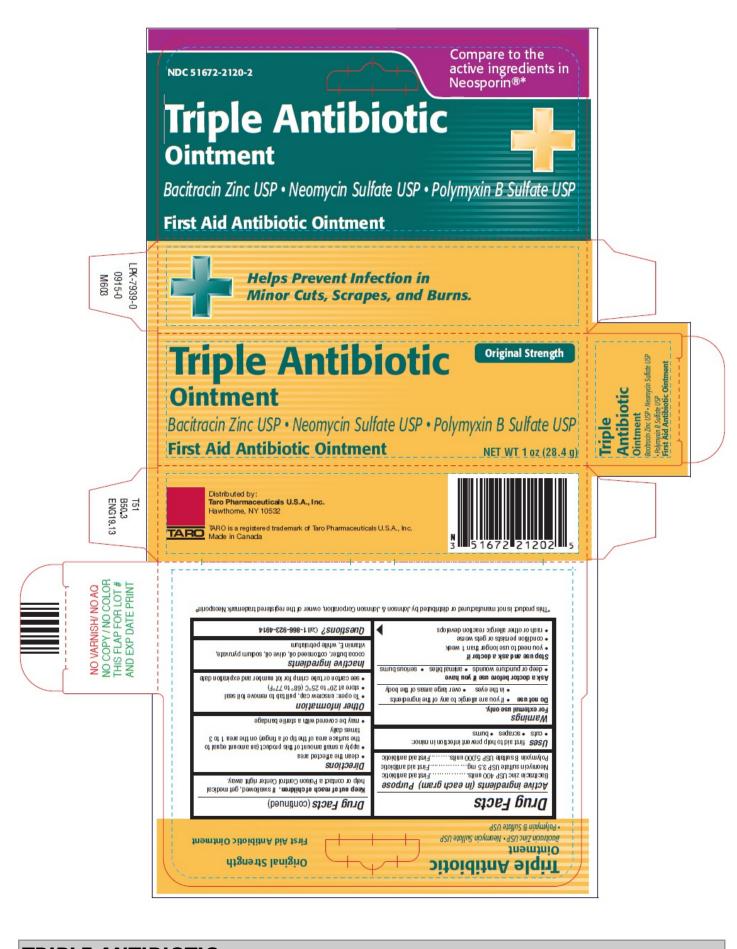
Original Strength

Triple Antibiotic Ointment

Bacitracin Zinc USP • Neomycin Sulfate USP • Polymyxin B Sulfate USP

First Aid Antibiotic Ointment

NET WT 1 oz (28.4 g)



TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, and polymyxin b sulfate ointment

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51672-2120 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|----------------------|------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I) | BACITRACIN | 400 [iU] in 1 g | |
| NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297) | NEOMYCIN | 3.5 mg in 1 g | |
| POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII: J2VZ 07J96K) | POLYMYXIN B | 5000 [iU] in 1 g | |

| Inactive Ingredients | | | |
|-------------------------------------|----------|--|--|
| Ingredient Name | Strength | | |
| COCOA BUTTER (UNII: 5120YT1CRR) | | | |
| COTTONSEED OIL (UNII: H3E878020N) | | | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | | | |
| SODIUM PYRUVATE (UNII: POD38AIF08) | | | |
| .ALPHATOCOPHEROL (UNII: H4N855PNZ1) | | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | | |

| Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------------------|---|---|-----------------------|
| NDC:51672- 2120-1 | 1 in 1 CARTON | 12/15/2015 | |
| | 14.2 g in 1 TUBE; Type 0: Not a Combination Product | | |
| NDC:51672- 2120-2 | 1 in 1 CARTON | 12/15/2015 | |
| | 28.4 g in 1 TUBE; Type 0: Not a Combination Product | | |
| NDC:51672- 2120-3 | 1 in 1 CARTON | 12/15/2015 | |
| | 60 g in 1 TUBE; Type 0: Not a Combination Product | | |
| NDC:51672- 2120-6 | 6 in 1 CARTON | 09/20/2021 | |
| | 0.9 g in 1 APPLICATOR; Type 0: Not a Combination Product | | |
| NDC:51672- 2120-8 | 15 in 1 CARTON | 09/20/2021 | |
| | 0.9 g in 1 APPLICATOR; Type 0: Not a Combination Product | | |
| NDC:51672- 2120-9 | 144 in 1 CARTON | 09/20/2021 | |
| | 0.9 g in 1 APPLICATOR; Type 0: Not a Combination Product | | |
| | 2120-1 NDC:51672- 2120-3 NDC:51672- 2120-6 NDC:51672- 2120-8 NDC:51672- | 2120-1 14.2 g in 1 TUBE; Type 0: Not a Combination Product NDC:51672- 2120-2 1 in 1 CARTON 28.4 g in 1 TUBE; Type 0: Not a Combination Product NDC:51672- 2120-3 1 in 1 CARTON 60 g in 1 TUBE; Type 0: Not a Combination Product NDC:51672- 2120-6 6 in 1 CARTON 0.9 g in 1 APPLICATOR; Type 0: Not a Combination Product NDC:51672- 2120-8 15 in 1 CARTON 0.9 g in 1 APPLICATOR; Type 0: Not a Combination Product NDC:51672- 2120-8 144 in 1 CARTON 0.9 g in 1 APPLICATOR; Type 0: Not a Combination Product NDC:51672- 2120-9 0.9 g in 1 APPLICATOR; Type 0: Not a Combination Product | NDC:51672-2120-1 |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M004 | 12/15/2015 | |
| OTC Monograph Drug | M004 | 12/15/2015 | |

Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

| Establishment | | | | |
|---------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Taro Pharmaceuticals Inc. | | 206263295 | manufacture(51672-2120) | |

Revised: 4/2024 Taro Pharmaceuticals U.S.A., Inc.