TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate, polymyxin b ointment Kareway Product, 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.

Pure-Aid Triple Antibiotic Ointment

Active ingredient

Bacitracin Zinc 400 units

Neomycin Sulfate 3.5mg

Polymyxin B Sulfate 5,000 units

Purpose

First aid antibiotic

First aid antibiotic

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

Ask a doctor before use if you have

- serious burns
- deep or puncture wounds
- animal bites

When using this product

- do not use in the eyes
- do not apply over large areas of the body

Stop use and ask a doctor if

• you need to use more than 1 week

- condition persists or gets worse
- symptoms persist for more than 1 week or clear up and occur again within a few days.
- 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

- adults and children 2 years of age or older:
- o clean the affected area
 - apply a small amount of this product (an amount equal tot the surface area of the tip of a finer) on the area 1 to 3 times daily
 - may be covered with a sterile bandage
- children under 2 years of age: ask a doctor

Other information

store at 59° to 77°F

Inactive ingredients

Cetyl alcohol, Glycerin, Light mineral oil, Myristoyl/palmitoyl oxostearamide/ arachamide MEA, Steareth-w, Squalane, Stearic acid, Tocopheryl acetate, White petrolatum

Package label panel

Triple Antibiotic Ointment



TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b ointment

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67510-0170 |
|-------------------------|----------------|--------------------|----------------|
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|----------------------|------------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I) | BACITRACIN | 400 [USP'U] 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 [USP'U] in 1 g | | |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | | |
| STEARETH-2 (UNII: V56DFE46J5) | | |
| SQUALANE (UNII: GW89575KF9) | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | |
| .ALPHATOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | |

| Packaging | | | | |
|-----------|----------------------|--|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:67510- 0170-1 | 1 in 1 BOX | 08/11/2011 | |
| 1 | | 28 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:67510- 0170-5 | 1 in 1 BOX | 08/11/2011 | |
| 2 | | 14 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:67510- 0170-3 | 1 in 1 BOX | 08/11/2011 | |
| 3 | | 9.4 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 | 08/10/2011 | | |
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Revised: 2/2023 Kareway Product, Inc.