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

Yiwu Ori-Power Medtech Co., Ltd.

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.

OP

Triple Antibiotic Ointment

Active Ingredients

(in each gram) Bacitracin zinc (bacitracin 400 units) Neomycin sulfate∏neomycin 3.5 mg∏

Polymyxin B sulfate (polymyxin B 5,000 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 eyes over large areas of the body
- if you are allergic to any of the ingredients
- longer than 1 week unless directed by a doctor.

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

• if the condition persists or gets worse

• a 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

Store at room temperature

Inactive Ingredients

Mineral oil, petrolatum, purified water



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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72459-102

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 | 0.0035 g 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 | |
| MINERAL OIL (UNII: T5L8T28FGP) | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | |
| WATER (UNII: 059QF0KO0R) | | |

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|---|---|----------------------|---|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:72459-102- 01 | 0.9 g in 1 POUCH; Type 0: Not a Combination Product | 08/28/2023 | |

| Marketing In | nformation | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part333B | 08/28/2023 | | |
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Labeler - Yiwu Ori-Power Medtech Co., Ltd. (560451976)

Revised: 8/2023 Yiwu Ori-Power Medtech Co., Ltd.