# TRIPLE ANTIBIOTIC- bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment NuCare Pharmaceuticals, 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.

-----

#### **Drug Facts**

# Active ingredients (In each gram)

Bacitracin 400

Neomycin 3.5 mg

Polymyxin B 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

#### Allergy alert:

do not use if you are allergic to any of the ingredients

#### Do not use

- in or near the eyes
- on large areas of the body

#### Consult a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

### When using this product

• do not use longer than 1 week

#### Stop use and consult a doctor if

- condition persists or gets worse
- symptoms last for more than 7 days or clear up and come back within a few days
- a rash or other allergic reaction develops

**Keep out of the reach of children.** If swallowed get medical help or contact a Poison Control Center immediately.

#### **Directions**

- clean the affected area
- apply a small amount (equal to surface area of tip of finger) on the area 1 to 3 times daily.
- may be covered with a sterile bandage

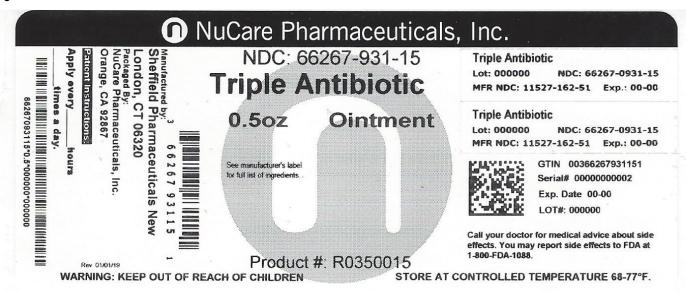
#### Other information

■ Store at a controlled room temperature 68°-77°F (20°-25°C)

#### **Inactive ingredient**

Petrolatum

#### Questions? 1-800-222-1087



#### TRIPLE ANTIBIOTIC

bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment

| Product Information     |                |                    |                              |  |
|-------------------------|----------------|--------------------|------------------------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:66267-931(NDC:11527-162) |  |
| Route of Administration | TOPICAL        |                    |                              |  |

| Active Ingredient/Active Moiety  |                          |                     |  |
|--|--------------------------|---------------------|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength            |  |
| BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO52I)   | BACITRACIN               | 400 [USP'U] in 1 g  |  |
| POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K) | POLYMYXIN B              | 5000 [USP'U] in 1 g |  |
| NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)       | NEOMYCIN                 | 3.5 mg in 1 g       |  |

| Inactive Ingredients          |                 |          |
|-------------------------------|-----------------|----------|
|                               | Ingredient Name | Strength |
| PETROLATUM (UNII: 4T6H12BN9U) |                 |          |

| Packaging                       |                    |   |                           |  |
|---------------------------------|--------------------|---|---------------------------|--|
| # Item Code Package Description |                    | <b>Marketing Start Date</b>                       | <b>Marketing End Date</b> |  |
| ı                               | 1 NDC:66267-931-15 | 14 g in 1 TUBE; Type 0: Not a Combination Product | 04/29/2019                |  |

| Marketing Information |  |                      |                    |  |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph final   | part333B                                 | 0 1/23/20 11         |                    |  |
|                       |  |                      |                    |  |

# Labeler - NuCare Pharmaceuticals,Inc. (010632300)

| Establishment               |         |           |                     |  |
|-----------------------------|---------|-----------|---------------------|--|
| Name                        | Address | ID/FEI    | Business Operations |  |
| NuCare Pharmaceuticals,Inc. |         | 010632300 | relabel(66267-931)  |  |

Revised: 1/2021 NuCare Pharmaceuticals,Inc.