TRIPLE ANTIBIOTIC- polymyxin b sulfate, bacitracin zinc and neomycin sulfate ointment Cosette Pharmaceuticals, Inc.

Triple Antibiotic Ointment
First Aid Antibiotic Ointment

ACTIVE INGREDIENT (in each gram)

Bacitracin zinc 400 units Neomycin 3.5 mg Polymyxin B sulfate 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
- 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

- 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

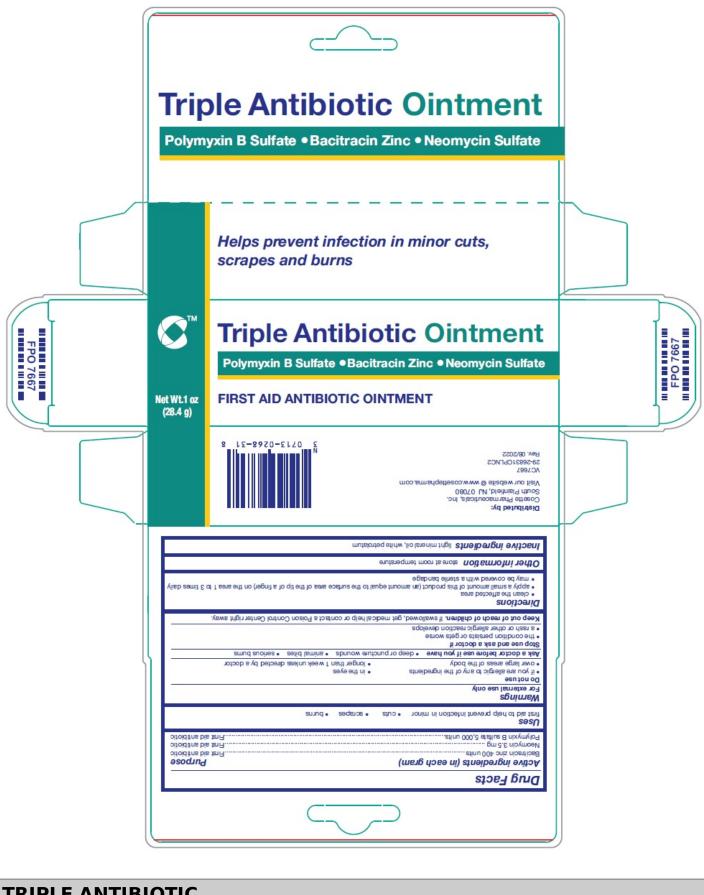
INACTIVE INGREDIENT

light mineral oil, white petrolatum

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Cosette Pharmaceuticals, Inc.

Triple Antibiotic Ointment FIRST AID ANTIBIOTIC OINTMENT Polymyxin B Sulfate, Bacitracin Zinc, Neomycin Sulfate Net Wt. 1 oz (28.4 g)



TRIPLE ANTIBIOTIC

polymyxin b sulfate, bacitracin zinc and neomycin sulfate ointment

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0713-0268 |
|-------------------------|----------------|--------------------|---------------|
| Route of Administration | TOPICAL | | |

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

| Inactive Ingredients | | |
|--------------------------------------|----------|--|
| Ingredient Name | Strength | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | |

| F | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | tem Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0713-0268- 31 | 1 in 1 CARTON | 01/11/1995 | |
| 1 | _ | 28.4 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 Drug | M004 | 01/11/1995 | |
| | | | |

Labeler - Cosette Pharmaceuticals, Inc. (116918230)

Registrant - Cosette Pharmaceuticals, Inc. (116918230)

| Establishment | | | | |
|--|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Cosette Pharmaceuticals NC Laboratories, LLC | | 079419931 | manufacture(0713-0268) | |

Revised: 12/2023 Cosette Pharmaceuticals, Inc.