TRIPLE ANTIBIOTIC PLUS - polymyxin b sulfate, bacitracin zinc, neomycin sulfate, pramoxine hcl ointment Cosette Pharmaceuticals, Inc.

Triple Antibiotic Plus Ointment Polymyxin B Sulfate • Bacitracin Zinc • Neomycin Sulfate • Pramoxine HCl

| Active ingredients (in each gram) | Purpose |
|-----------------------------------|----------------------|
| Bacitracin zinc 500 units | First aid antibiotic |
| Neomycin 3.5 mg | First aid antibiotic |
| Polymyxin B sulfate 10,000 units | First aid antibiotic |
| Pramoxine hydrochloride 10.0 mg | Topical analgesic |

USES

first aid to help prevent infection and provide temporary relief of pain or discomfort 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
- symptoms persist for more than 1 week, or clear up and occur again within a few days
- 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

- adults and children 2 years of age and older
 - 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
- children under 2 years of age: consult a doctor

OTHER INFORMATION

store at room temperature

INACTIVE INGREDIENT

light mineral oil, white petrolatum

PRINCIPAL DISPLAY PANEL

Triple Antibiotic Plus Ointment
Polymyxin B Sulfate • Bacitracin Zinc • Neomycin Sulfate • Pramoxine HCI
FIRST AID ANTIBIOTIC / PAIN RELIEVING OINTMENT
Net Wt. 1 oz
(28.4 g)



TRIPLE ANTIBIOTIC PLUS

polymyxin b sulfate, bacitracin zinc, neomycin sulfate, pramoxine hcl ointment

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0713-0622 |
|-------------------------|----------------|--------------------|---------------|
| 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 | 10000 [USP'U] in 1 g | |
| Bacitracin Zinc (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I) | Bacitracin Zinc | 500 [USP'U] in 1 g | |
| Neomycin (UNII: I16QD7X297) (Neomycin - UNII:I16QD7X297) | Neomycin | 3.5 mg in 1 g | |
| Pramoxine Hydrochloride (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056) | Pramoxine Hydrochloride | 10 mg in 1 g | |

| Inactive Ingredients | | | | |
|--------------------------------------|----------|--|--|--|
| Ingredient Name | Strength | | | |
| Light Mineral Oil (UNII: N6K5787QVP) | | | | |
| Petrolatum (UNII: 4T6H12BN9U) | | | | |

| l | Packaging | | | | |
|---|-----------|----------------------|---|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:0713-0622- 31 | 28.4 g in 1 TUBE; Type 0: Not a Combination Product | 02/28/1998 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M004 | 02/28/1998 | |
| | | | |

Labeler - Cosette Pharmaceuticals, Inc. (116918230)

Registrant - Cosette Pharmaceuticals, Inc. (116918230)

| Establishment | | | | |
|--|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Cosette Pharmaceuticals NC Laboratories, LLC | | 079419931 | MANUFACTURE(0713-0622) | |

Revised: 12/2023 Cosette Pharmaceuticals, Inc.