

**TRIPLE ANTIBIOTIC - bacitracin zinc neomycin sulfate polymyxin b sulfate
pramoxine hcl ointment
Encube Ethicals, Inc.**

Triple antibiotic ointment + pain relief

Active ingredients (in each gram)

Bacitracin zinc USP, 500 units

Neomycin 3.5 mg

Polymyxin B sulfate USP, 10,000 units

Pramoxine hydrochloride USP, 10 mg

Purposes

First aid antibiotic

Pain reliever

Uses

First aid to help prevent infection for the temporary relief of pain in minor ■ burns ■ cuts ■ scrapes

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

Ask a doctor before use if you have

- deeper puncture wounds
- animal bites
- serious burns

Stop use and ask doctor if

- you need to use longer than one week
- condition persists or gets worse
- rash or other allergic reaction develops
- symptoms persist for more than one week, or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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: ask a doctor

Other information

- store at 15°C to 30°C (59°F to 86°F)
- before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredient

white petrolatum

Questions or comments?

Call - 1-833-285-4151 Monday-Friday 9AM-5PM EST

PRINCIPAL DISPLAY PANEL

Triple Antibiotic

Ointment + Pain Relief

NET WT. 0.5 OZ (14 g)

NDC 21922-101-04



Maximum Strength Triple Antibiotic Ointment + Pain Relief

BACITRACIN ZINC • NEOMYCIN SULFATE • POLYMYXIN B SULFATE • PRAMOXINE HCl
FIRST AID ANTIBIOTIC / PAIN-RELIEVING OINTMENT

NET WT. 0.5 OZ (14 g)

Compare to the active ingredients in
Neosporin® + Pain Relief

NDC 21922-101-04

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For external use only
Helps prevent infection and
temporarily relieves pain of minor
cuts, scrapes, and burns

EMBOSSING
AREA

Mfg.Lic.No.: 362



Manufactured by:
Encube Ethicals Pvt. Ltd.
Plot No. C-1, Madkaim
Industrial Estate, Madkaim,
Post: Mardol, Ponda,
Goa - 403 404, India.

Distributed by:
Encube Ethicals, Inc.
200 Meredith Drive,
Suite 202, Durham,
NC 27713, USA

ECN3B/00

++This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Neosporin®.

| | |
|-------------------------------|---|
| Drug Facts | Active ingredients (in each gram) Bacitracin zinc USP 500 units Neomycin 3.5 mg Polymyxin B sulfate USP 10,000 units Pramoxine hydrochloride USP 10 mg Pain reliever |
| Uses | First aid to help prevent infection for the temporary relief of pain in minor ■ burns ■ cuts ■ scrapes |
| 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 |
| Other information | Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites ■ serious burns Stop use and ask a doctor if ■ you need to use longer than one week ■ condition persists or gets worse ■ rash or other allergic reaction develops ■ symptoms persist for more than one week or clear up and occur again within a few days |
| 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, ask a doctor |
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Triple Antibiotic
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NET WT. 1 OZ (28 g)

NDC 21922-101-05



Maximum Strength Triple Antibiotic Ointment + Pain Relief

BACITRACIN ZINC • NEOMYCIN SULFATE • POLYMYXIN B SULFATE • PRAMOXINE HCl
FIRST AID ANTIBIOTIC / PAIN-RELIEVING OINTMENT

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TRIPLE ANTIBIOTIC

bacitracin zinc neomycin sulfate polymyxin b sulfate pramoxine hcl ointment

Product Information

| | | | | |
|--|---|---|-----------------------------|---------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:21922-101 | |
| Route of Administration | TOPICAL | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I) | | BACITRACIN | 500 [USP'U] in 1 g | |
| NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297) | | NEOMYCIN | 3.5 mg in 1 g | |
| POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ 07J96K) | | POLYMYXIN B | 10000 [USP'U] in 1 g | |
| PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056) | | PRAMOXINE HYDROCHLORIDE | 10 mg in 1 g | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| WHITE PETROLATUM (UNII: B6E5W8RQJ4) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:21922-101-04 | 1 in 1 CARTON | 03/06/2025 | |
| 1 | | 14 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:21922-101-05 | 1 in 1 CARTON | 03/06/2025 | |
| 2 | | 28 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 | | 03/06/2025 | |

Labeler - Encube Ethicals, Inc. (116982244)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------|---------|-----------|---|
| Encube Ethicals Private Limited | | 725076298 | analysis(21922-101) , label(21922-101) , manufacture(21922-101) , pack(21922-101) |