

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

Trifecta Pharmaceuticals Usa Llc

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.

Triple Antibiotic Ointment

DRUG FACTS

Active ingredient (each gram contains)

Bacitracin zinc 400 units
Neomycin sulfate 3.5 mg
Polymyxin B sulfate 5,000 units

Purpose

First aid antibiotic

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Uses first aid to help prevent infection in minor: ● cuts ● scrapes ● burns

Warnings For external use only.

Do not use ● in the eyes ● over large areas of the body
● if you are allergic to any of the ingredients.

Ask a doctor before use if you have

● deep or puncture wounds ● animal bites ● serious burns.

Stop use and ask a doctor if ● condition persists or gets worse

● you need to use longer than 1 week
● a rash or other allergic reaction develops

Directions

● clean the affected area and dry thoroughly.
● 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

Inactive ingredient Light Mineral Oil, Petrolatum

Other information

- To open: unscrew cap, pull tab to remove foil seal
- store at 20° to 25°C (68° to 77°F)
- see carton or tube crimp for lot number and expiration date

Questions? Call 1-888-296-9067

Distributed by:

Trifecta Pharmaceuticals USA™

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL 33301, USA

www.trifecta-pharma.com

Packaging

Triple Antibiotic Ointment
BACITRACIN ZINC • NEOMYCIN SULFATE • POLYMYXIN B SULFATE
FIRST AID ANTIBIOTIC OINTMENT

100% GUARANTEED

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

TRIPLE ANTIBIOTIC

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Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69396-015 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------------|
| BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I) | BACITRACIN | 400 [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 | 5000 [USP'U] in 1 g | |
|--|--|---|------------------------|--------------------|
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | | | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:69396-015-05 | 1 in 1 BOX | 03/18/2016 | |
| 1 | | 15 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:69396-015-20 | 1 in 1 BOX | 03/18/2016 | |
| 2 | | 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 final | part333B | 03/18/2016 | | |

Labeler - Trifecta Pharmaceuticals Usa Llc (079424163)

Revised: 1/2023

Trifecta Pharmaceuticals Usa Llc