

## **TRIPLE ANTIBIOTIC- bacitracin zinc, neomycin sulfate and polymyxin b sulfate ointment**

**Orazen 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.*

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### **Triple Antibiotic**

#### **Active Ingredients (in each gram)**

Bacitracin Zinc      400 units

Neomycin Sulfate    5 mg

(3.5 mg of Neomycin base)

Polymyxin B Sulfate 5000 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**

- in the eyes
- if you are allergic to any of the ingredients
- longer than 1 week unless directed by a doctor
- over large areas of the body

**Ask a doctor before use if you have** deep or puncture wounds, animal bites, or 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 20°C to 25°C (68°F to 77°C)
- do not use if tube seal under cap is broken, missing or if tube tip is cut prior to opening

**Inactive Ingredients**

cocoa butter, cottonseed oil, olive oil, sodium pyruvate, vitamin E, white petrolatum

**PRINCIPAL DISPLAY PANEL**

Triple Antibiotic Ointment

Bacitracin Zinc, Neomycin Sulfate and Polymyxin B Sulfate

First Aid Antibiotic Ointment

NET WT 0.5 oz (14.2 g)

**QUALITY GUARANTEED**

Compare to the Active Ingredients in Neosporin®\*

**24 HOUR Infection Protection**

# Triple Antibiotic Ointment

Bacitracin Zinc, Neomycin Sulfate, Polymyxin-B Sulfate  
First Aid Antibiotic Ointment

**24 HOUR Infection Protection**

**Helps Prevent Infection in Minor Cuts, Scrapes and Burns**

NET WT 0.5 oz (14.2 g)

**L.D. DrugStore**

Product distributed by:

97310C-US-06-18-A

LIP Drug Store Products, Inc.  
9300 Earhart Lane SW  
Cedar Rapids, IA 52404

Made in India



<p><b>Drug Facts (continued)</b></p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ clean the affected area</li> <li>■ 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</li> <li>■ may be covered with a sterile bandage</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store at 20°C to 25°C (68°F to 77°F)</li> <li>■ do not use if tube seal under cap is broken, missing or if tube tip is cut prior to opening</li> </ul> <p><b>Inactive ingredients</b> cocoa butter, cottonseed oil, olive oil, sodium pyruvate, vitamin E, white petrolatum</p> <p><b>Questions?</b> call toll-free 1-877-507-6516 (M-F 8AM-4:30PM CST)</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each gram) Purpose</b></p> <p>Bacitracin Zinc 400 units.....First aid antibiotic</p> <p>Neomycin Sulfate 5 mg (3.5 mg of Neomycin base).....First aid antibiotic</p> <p>Polymyxin-B Sulfate 5000 units.....First aid antibiotic</p> <p><b>Use</b></p> <p>first aid to help prevent infection in</p> <ul style="list-style-type: none"> <li>■ minor cuts</li> <li>■ scrapes</li> <li>■ burns</li> </ul> <p><b>Warnings</b></p> <p>For external use only.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ in the eyes</li> <li>■ over large areas of the body</li> <li>■ if you are allergic to any of the ingredients</li> <li>■ longer than 1 week unless directed by a doctor</li> </ul> <p><b>Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ the condition persists or gets worse</li> <li>■ a rash or other allergic reaction develops</li> </ul>
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\*This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company - A Division of Johnson & Johnson Consumer Companies, Inc., owner of the registered trademark Neosporin®.

## TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate and polymyxin b sulfate ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71927-003
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BACITRACIN ZINC</b> (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [USP'U] in 1 g
<b>NEOMYCIN SULFATE</b> (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g
<b>POLYMYXIN B SULFATE</b> (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [USP'U] in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>COTTONSEED OIL</b> (UNII: H3E878020N)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>SODIUM PYRUVATE</b> (UNII: POD38AIF08)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71927-003-02	1 in 1 CARTON	07/12/2018	
1		14.2 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	07/12/2018	

**Labeler** - Orazen Inc (080916640)

**Registrant** - Anicare Pharmaceuticals Pvt. Ltd (916837425)

### Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(71927-003)

Revised: 2/2022

Orazen Inc