

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

**Anicare Pharmaceuticals Pvt. Ltd**

*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 First Aid Antibiotic Ointment**

***Active Ingredients***

Bacitracin Zinc 400U

Neomycin 3.5 mg

Polymyxin B Sulfate 5000U

***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 on**

- on deep puncture wounds, animal bites, or serious burns

**Stop use and consult a doctor** if the condition persists or gets worse, or if 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 and dry thoroughly
- May be covered with a sterile bandage
- 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

***Other Information***

- Store at 20°C to 25°C (68°F to 77°C)
- Lot No. & Exp. Date: see crimp of tube

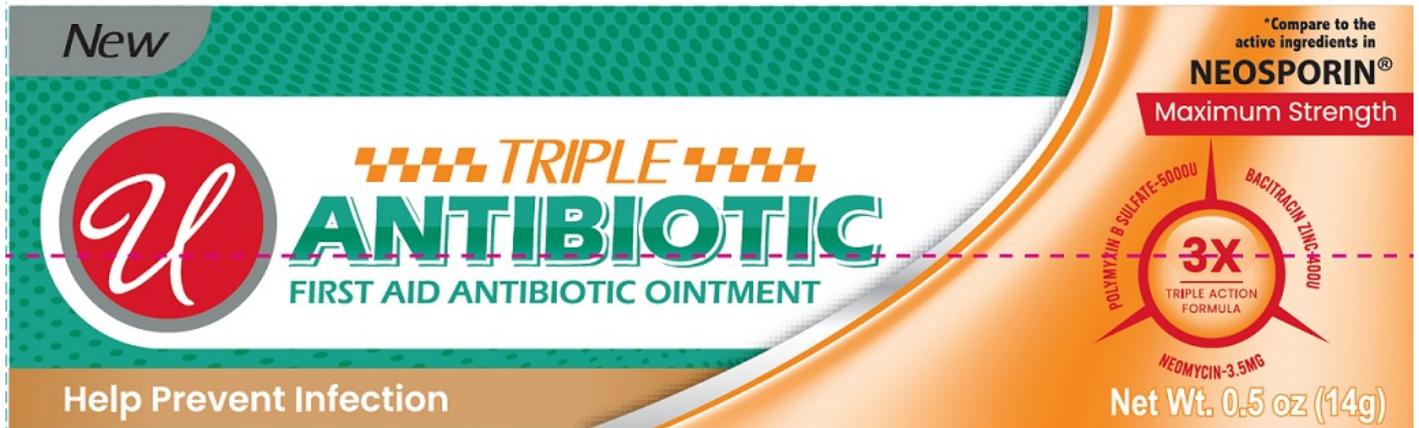
***Inactive Ingredients***

cocoa butter, cotton seed oil, olive oil, sodium pyruvate, vitamin E, white petrolatum, hard paraffin, mineral oil

**PRINCIPAL DISPLAY PANEL**

Triple Antibiotic First Aid Antibiotic Ointment

NET WT 0.5 OZ (14 g)



**Drug Facts**

**Active Ingredients**

Bacitracin Zinc - 400U.....	First Aid Antibiotic
Neomycin - 3.5mg.....	First Aid Antibiotic
Polymyxin B Sulfate 5000U.....	First Aid Antibiotic

**Purpose**

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**Inactive Ingredients** cocoa butter, cottonseed oil, olive oil, sodium pyruvate, vitamin E, white petrolatum, hard paraffin, mineral oil

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

Distributed By: Universal Distribution Center, 96 Distribution Boulevard, Edison, NJ 08817 www.universalbrandsusa.com

Lot No. & Exp. Date: see crimp of tube.

Item#86072

Made in India

**TRIPLE ANTIBIOTIC FIRST AID ANTIBIOTIC**

bacitracin zinc, neomycin and polymyxin b sulfate ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:47046-154
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6RWO52I)	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:J2VZ07J96K)	POLYMYXIN B	5000 [USP'U] in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
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<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>WHITE PETROLATUM</b> (UNII: B6E5W8RQJ4)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47046-154-02	1 in 1 BOX	12/09/2020	
1	NDC:47046-154-01	14 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	12/09/2020	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(47046-154)

Revised: 12/2020

Anicare Pharmaceuticals Pvt. Ltd