

**BUDPAK TRIPLE ANTIBIOTIC MAXIMUM STRENGTH- bacitracin zinc, neomycin sulfate and polymyxin b sulfate ointment**  
**Budpak 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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***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
- 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)
- Lot No. Exp. Date: see crimp of tube

***Inactive Ingredients***

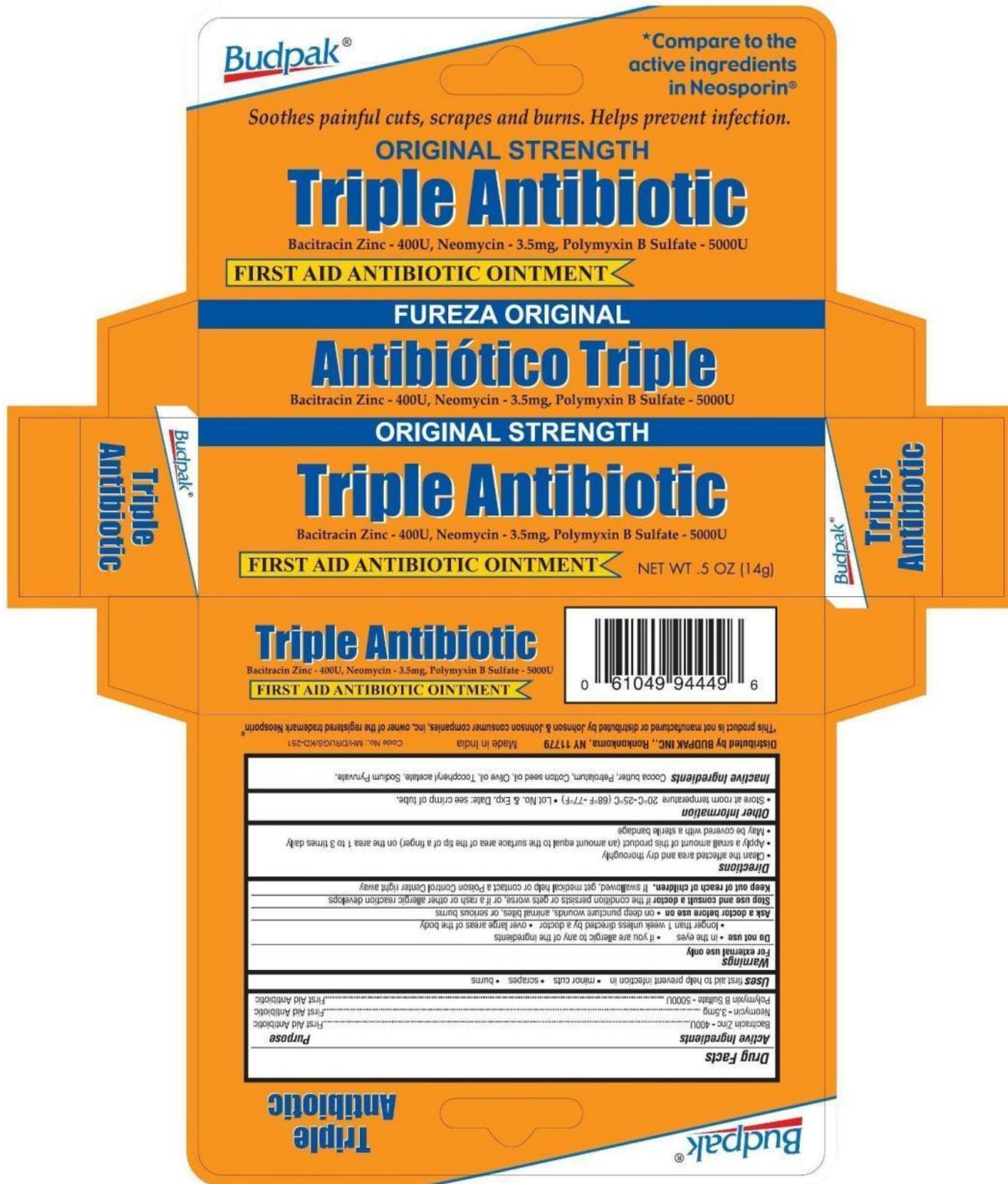
Cocoa butter, Petrolatum, Cottonseed oil, Olive oil, Tocopheryl acetate, Sodium pyruvate.

**PRINCIPAL DISPLAY PANEL**

Budpak Triple Antibiotic

First Aid Antibiotic Ointment

NET WT 0.5 OZ (14 g)



**BUDPAK TRIPLE ANTIBIOTIC MAXIMUM STRENGTH**

bacitracin zinc, neomycin sulfate and polymyxin b sulfate ointment

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27293-024
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:J2VZ07J96K)	POLYMYXIN B	5000 [USP'U] in 1 g

## Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-024-01	1 in 1 BOX		
1	NDC:27293-024-14	14 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	06/10/2013	

**Labeler** - Budpak Inc. (183224849)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-024)