

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

Universal Distribution Center 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 First Aid 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
- 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, Cotton seed oil, Olive oil, Tocopheryl acetate, Sodium pyruvate.

PRINCIPAL DISPLAY PANEL

Triple Antibiotic First Aid Ointment

NET WT 0.5 OZ (14 g)



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Drug Facts

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Code No.: MH/DRUGS/KD-251

Distributed by: Universal Distribution Center, Edison, NJ

Item#86072

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Made in India

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52000-019	
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	
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:52000-019-37	1 in 1 BOX	02/14/2022	
1	NDC:52000-019-36	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	04/15/2015		

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52000-019)