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.

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

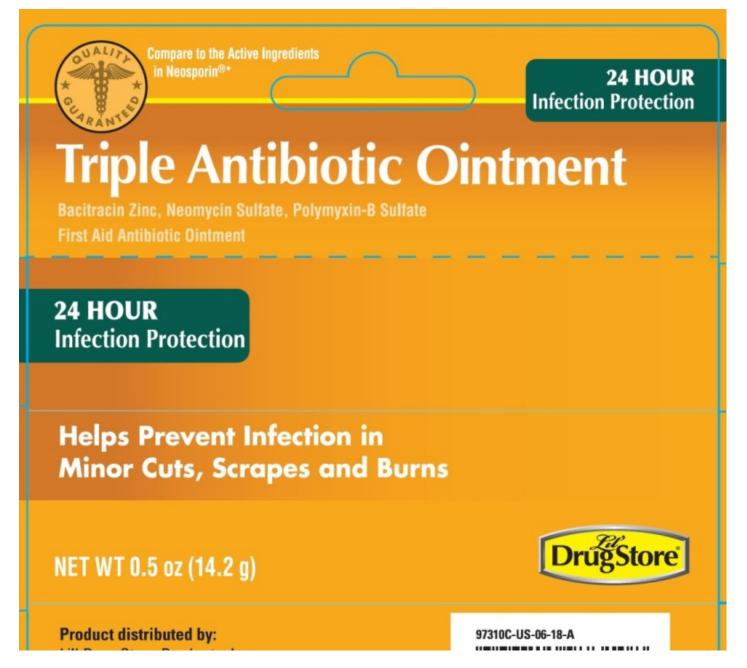
PRINCIPAL DISPLAY PANEL

Triple Antibiotic Ointment

Bacitracin Zinc, Neomycin Sulfate and Polymyxin B Sulfate

First Aid Antibiotic Ointment

NET WT 0.5 oz (14.2 g)





Lil' Drug Store Products, Inc. 9300 Earhart Lane SW

Made in India

Cedar Rapids, IA 52404

	Questions? Call toll-free 1-877-507-6516 (M-F 8AM-4:30PM CST)
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USC first aid to help prevent infection in eq minor cuts scrapes burns th	 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
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	Drug Facts (continued)

TRIPLE ANTIBIOTIC

Inactive Ingredients

bacitracin zinc, neomycin sulfate and polymyxin b sulfate ointment

Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:71927-003				
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Active ingreatent/Active	lindicty		Basis of					
lin er vie	diaut Nama		Dasis Ul	<u> </u>				
ingre	dient Name		Strength	Strength				
BACITRACIN ZINC (UNII: 89Y4M		H6RW052I)	Strength BACITRACIN	Strength 400 [USP'U] in 1 g				
	234ES) (BACITRACIN - UNII:58							
BACITRACIN ZINC (UNII: 89Y4M2	234ES) (BACITRACIN - UNII:58 Y626693) (NEOMYCIN - UNII:II	16QD7X297)	BACITRACIN	400 [USP'U] in 1 g				

	Strength		
COCOA BUTTER (U			
COTTONSEED OIL	(UNII: H3E878020N)		
OLIVE OIL (UNII: 6L	YK2W1W1E)		
SODIUM PYRUVAT			
ALPHATOCOPHE	ROL ACETATE (UNII: 9E8X80D2L0)		
PETROLATUM (UNI	: 4T6H12BN9U)		
Packaging			
Гаскаушу			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:71927-003- 02	1 in 1 CARTON	07/12/2018	
_	14.2 g in 1 TUBE; Type 0: Not a Combination		
1	Product		
1	Product		
1	Product		
-	nformation		
-		Marketing Start Date	Marketing End Date

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