BACITRACIN ZINC, NEOMYCIN SULFATE AND POLYMYXIN B SULFATE- bacitracin zinc, neomycin sulfate and polymyxin b sulfate ointment Central Texas Community Health Centers

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 Ointment

Active ingredient (in ea. gram)

Bacitracin Zinc 400 Units

Neomyxin Sulfate 5mg (Equivalent to 3.5 mg Neomyxin)

Polymyxin B Sulfate 5000 Units

Purpose

First Aid Antibiotic

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Ask a doctor before use:

First aid to help prevent infection in:

- Minor cuts
- scrapes
- burns

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Other information

- store at controlled room temperature 15°-30° C (59°-86° F)
- avoid excessive heat and humidity

Inactive ingredients:

Hard Paraffin, Liquid Paraffin, White Soft Paraffin

Keep Out Of Reach Of Children

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Warnings

For external use only

Dosage and Administration

- clean the affected areas
- apply a small amount of product (an amount equal to the surface area of the tip of the finger) on the area 1 to 3 times daily
- may be covered with a sterile bandage

Do Not Use:

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

Stop use and ask a doctor if

• Stop use and ask a doctor if condition persists or gets worse, or if a rash or other allergic reaction occurs

PRINCIPAL DISPLAY PANEL - 15 g Tube Box Label

Austin/Travis Co. Health & Human Services Dept. 1000 Toyath St. Austin, TX 78702 512-972-6206

Triple
Antibiotic
Oint #15g

Date:

Name: Dr.

USE AS DIRECTED

10/2018

HW15015

Triple Antibiotic Ointment #15 g NDC 76413-347-01

Batch: 08311701 Lot: HW15015 Exp: 10/2018 Dynarex

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

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Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76413-347(NDC:67777-217)

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	BACITRACIN	400 [iU] in 1 g	
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	5 mg in 1 g	
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
PETRO LATUM (UNII: 4T6H12BN9U)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:76413-347-01	1 in 1 BOX	04/18/2016	
1	15 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	12/01/2009

Labeler - Central Texas Community Health Centers (079674019)

Establishment			
Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-347), RELABEL(76413-347)

Revised: 9/2017

Central Texas Community Health Centers