TRIPLE ANTIBIOTIC GRX- bacitracin zinc, neomycin sulfate, and polymyxin b sulfate ointment
Geritrex 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 GRX

Drug Facts

Active ingredients (in each gram)	Purpose
Bacitracin 400 units	First aid antibiotic
Neomycin 3.5 mg	First aid antibiotic
Polymyxin B 5,000 units	First aid antibiotic

Use

first aid to help prevent infection in minor:
- cuts
- scrapes
- burns

Warnings

For external use only.

Do not use
- if you are allergic to any of the ingredients
- in the eyes
- over large areas of the body

Ask a doctor before use if you have
- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if
- you need to use longer than 1 week
- condition persists or gets worse
- 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
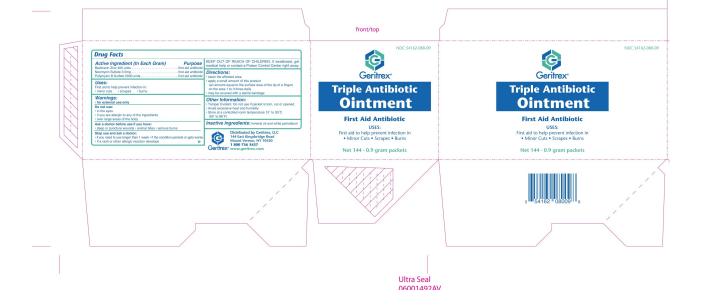- may be covered with a sterile bandage

Other information

- store at 15° to 30°C (59° to 86° F)

Inactive ingredients

Mineral oil, petrolatum

Questions?

call **1-800-736-3437**

NDC 54162-080-09

Triple Antibiotic Ointment

Geritrex®

First Aid Antibiotic
NET WT 0.9g (1/32 OZ)

USES:
First aid to help prevent infection in
• Minor Cuts • Scrapes • Burns

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1-5/16"

2-1/2"

Active Ingredient: (In each gram) Bacitracin Zinc 400 units, Neomycin 3.5 mg, Polymyxin B Sulfate 5000 units.
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. • over large areas of the body • **Ask a doctor before use if you have:** • deep or puncture wounds • animal bites • serious burns **Stop use and ask a doctor:** • if you need to use longer than 1 week • if the condition persists or gets worse • 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 • apply a small amount (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: Tamper Evident. Do not use if packet is torn, cut or opened. Store at a controlled room temperature 15˚ to 30˚C (59˚ to 86˚F).
Inactive Ingredients: mineral oil, white petrolatum

Distributed by Geritrex, LLC
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TRIPLE ANTIBIOTIC GRX
bacitracin zinc, neomycin sulfate, and polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54162-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Bacitracin Zinc (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I)	Bacitracin	400 [iU] 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 [iU] in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
Petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-080-09	0.9 g in 1 POUCH; Type 0: Not a Combination Product	12/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333B	12/01/2017	

Labeler - Geritrex LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-080)

Revised: 12/2017   Geritrex LLC