TRIPLE ANTIBIOTIC- first aid antibiotic ointment
Dynarex Corporation

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.

1184 Triple Antibiotic NDC 67777-118-40

Active Ingredients

Bacitracin Zinc (400 units per gram)

Neomycin Sulfate 5mg (equivalent to 3.5mg Neomycin per gram)

Polymyxin B Sulfate (5000 units per gram)

Purpose

First Aid Antibiotics

Uses:

First aid to help prevent infection in minor cuts, scrapes, and burns

Warnings:

For external use only

Do not use

- In the eyes or apply over large areas of the body
- If you are allergic to any of the ingredients
- Longer than 1 week unless directed by a doctor

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, or if a rash or other allergic reaction develops

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.

Inactive Ingredient

White Petrolatum

Label

TRIPLE ANTIBIOTIC

first aid antibiotic ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-118
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 in 1000 mg
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1000 mg
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 in 1000 mg

Inactive Ingredients	
Ingredient Name	**Strength**
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-118-40	72 in 1 CASE	01/23/2018	
1		14000 mg 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	01/23/2018	

Labeler - Dynarex Corporation (008124539)

Revised: 2/2019 Dynarex Corporation