

BACITRACIN ZINC, NEOMYCIN SULFATE AND POLYMYXIN B SULFATE - bacitracin zinc, neomycin sulfate and polymyxin b sulfate 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.

Triple Antibiotic

Active ingredient (in ea. gram)

Bacitracin Zinc 400 Units

Neomycin Sulfate 5mg (Equivalent to 3.5 mg Neomycin)

Polymyxin B Sulfate 5000 Units

Purpose

antibacterial

antibacterial

antibacterial

Uses triple antibiotic :

First aid to help prevent infection in:

- Minor cuts
- scrapes
- burns

Ask a doctor before use:

- in case of deep or puncture wounds
- animal bites
- serious burns

Other information

- store at controlled room temperature 15°-30° C (59°-86° F)
- avoid excessive heat and humidity
- Tamper Evident. Do not use if packet is torn, cut or open.

Inactive ingredients:

White petrolatum

Directions triple antibiotic:

- clean 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

KEEP OUT OF REACH OF CHILDREN If swallowed, get medical help or contact a Poison Control Center right away.

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

Warnings

For external use only

Principal Display Panel

Triple Antibiotic

<p>Drug Facts</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left;">Active Ingredient</th> <th style="text-align: left;">Purpose</th> </tr> <tr> <td>Bacitracin Zinc 400 units</td> <td>antibacterial</td> </tr> <tr> <td>Neomycin Sulfate 5 mg (Equivalent to 3.5 mg Neomycin)</td> <td>antibacterial</td> </tr> <tr> <td>Polymyxin B Sulfate 5000 unit</td> <td>antibacterial</td> </tr> </table> <p>Uses: First aid to help prevent infection in: • minor cuts • scrapes • burns</p> <p>Warnings: FOR EXTERNAL USE ONLY.</p> <p>Do not use: • in the eyes • over large areas of the body • if you are allergic to any of the ingredients, due to the possibility of anaphylactic shock • longer than 1 week unless directed by a doctor</p> <p>Stop use and ask a doctor:</p> <ul style="list-style-type: none"> • before use in case of deep puncture wounds, animal bites or serious burns • if the condition persists or gets worse • if a rash or other allergic reaction develops ▶ 	Active Ingredient	Purpose	Bacitracin Zinc 400 units	antibacterial	Neomycin Sulfate 5 mg (Equivalent to 3.5 mg Neomycin)	antibacterial	Polymyxin B Sulfate 5000 unit	antibacterial	<p>Drug Facts (continued)</p> <p>KEEP OUT OF REACH OF CHILDREN.</p> <p>If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions:</p> <ul style="list-style-type: none"> • 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 <p>Other Information:</p> <ul style="list-style-type: none"> • Tamper Evident. Do not use if packet is torn, cut or opened. • Avoid excessive heat and humidity • Store at a controlled room temperature 15° to 30°C (59° to 86°F) <p>INACTIVE INGREDIENTS white petrolatum.</p>	<div style="display: flex; align-items: center; justify-content: center;"> <div style="border: 1px solid red; border-radius: 50%; padding: 5px; margin-right: 10px; color: white; font-weight: bold;">144</div> <div style="font-weight: bold;">Packets</div> </div> <p>Net Wt 0.9 gram</p> <p style="color: red; font-size: 1.2em; font-weight: bold; margin-top: 20px;">Triple Antibiotic Ointment</p> <p style="color: red; font-weight: bold; margin-top: 5px;">First Aid Antibiotic</p> <div style="margin-top: 20px;"> <p>Manufactured for: Dynarex Corporation Orangeburg, NY 10962 www.dynarex.com</p> </div> <p style="font-weight: bold; margin-top: 20px;">Reorder No. 1182</p>
Active Ingredient	Purpose									
Bacitracin Zinc 400 units	antibacterial									
Neomycin Sulfate 5 mg (Equivalent to 3.5 mg Neomycin)	antibacterial									
Polymyxin B Sulfate 5000 unit	antibacterial									
<p>Reorder No. 1182</p>	<p>Made in USA</p>	<p>NDC# 67777-240-02</p>								

BACITRACIN ZINC, NEOMYCIN SULFATE AND POLYMYXIN B SULFATE				
bacitracin zinc, neomycin sulfate and polymyxin b sulfate ointment				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-240	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN ZINC - UNII:89Y4M234ES)	BACITRACIN ZINC	400 [iU] in 1 g		
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g		
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B SULFATE	5000 [iU] in 1 g		
Inactive Ingredients				
Ingredient Name	Strength			
PETROLATUM (UNII: 4T6H12BN9U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-240-01	12 in 1 CASE		
1		144 in 1 BOX		
1		0.5 g in 1 PACKET		
2	NDC:67777-240-02	12 in 1 CASE		
2		144 in 1 BOX		
2		0.9 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	03/16/2011	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Revised: 3/2011

Dynarex Corporation