

BACITRACIN ZINC - bacitracin zinc 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.

Bacitracin Zinc

Active ingredient

Bacitracin Zinc 500 Units

Purpose

Antibacterial

Uses:

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 and serious burns
- if the condition persists or gets worse
- if a rash or any other allergic reaction develops

Other information

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

Inactive ingredients

White Petrolatum

Indications and Usage

- For first aid to help prevent infection in minor skin abrasions and rashes.

Directions:

- clean the affected area
- apply a small amount of this product (an amount equal to the surface area of the tip of the finger) on the area 1-3 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.

- **for external use only**

Do not use:

Do not use:

- in the eyes
- over large area 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

Principal Display Panel

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<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left;">Drug Facts</th> </tr> <tr> <td style="width: 50%;">Active Ingredient Bacitracin Zinc 500 units</td> <td style="width: 50%;">Purpose antibacterial</td> </tr> <tr> <td colspan="2">Uses: First aid to help prevent infection in: • minor cuts • scrapes • burns</td> </tr> <tr> <td colspan="2">Warnings: FOR EXTERNAL USE ONLY.</td> </tr> <tr> <td colspan="2">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</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor:</td> </tr> <tr> <td colspan="2">• 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 ▶</td> </tr> </table>	Drug Facts		Active Ingredient Bacitracin Zinc 500 units	Purpose antibacterial	Uses: First aid to help prevent infection in: • minor cuts • scrapes • burns		Warnings: FOR EXTERNAL USE ONLY.		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		Stop use and ask a doctor:		• 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 ▶		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left;">Drug Facts (continued)</th> </tr> <tr> <td colspan="2">KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">Directions:</td> </tr> <tr> <td colspan="2">• clean the affected area</td> </tr> <tr> <td colspan="2">• 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</td> </tr> <tr> <td colspan="2">• may be covered with a sterile bandage</td> </tr> <tr> <td colspan="2">Other Information:</td> </tr> <tr> <td colspan="2">• 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)</td> </tr> <tr> <td colspan="2">INACTIVE INGREDIENTS white petrolatum.</td> </tr> </table>	Drug Facts (continued)		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:		• 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)		INACTIVE INGREDIENTS white petrolatum.		<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>144 Packets</p> </div> <div> <p>Net Wt 0.9 gram</p> </div> </div> <div style="text-align: center; margin-top: 20px;"> <p>Bacitracin Zinc Ointment First Aid Antibiotic</p> </div> <div style="text-align: center; margin-top: 20px;"> <p>Manufactured for: Dynarex Corporation Orangeburg, NY 10962 www.dynarex.com</p> </div> <div style="text-align: center; margin-top: 20px;">  </div>
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Reorder No. 1171	Made in USA	NDC# 67777-239-01	Reorder No. 1171																															

BACITRACIN ZINC				
bacitracin zinc ointment				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-239	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN ZINC - UNII:89Y4M234ES)	BACITRACIN ZINC	500 [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:67777-239-01	12 in 1 CASE		

1	144 in 1 BOX		
1	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	12/01/2009	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Revised: 3/2011

Dynarex Corporation