

**BACITRACIN ZINC AND POLYMYXIN B SULFATE - bacitracin zinc and polymyxin b sulfate ointment**

**H.J. Harkins Company, Inc.**

*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.*

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**Fougera® Double Antibiotic Ointment  
(Bacitracin Zinc and Polymyxin B Sulfate Ointment USP)**

**Drug Facts**

**Active ingredients (in each gram)**

Bacitracin Zinc (equal to 500 bacitracin units)

Polymyxin B Sulfate (equal to 10,000 polymyxin B units)

**Purpose**

Antibiotic

Antibiotic

**Uses** first aid to help prevent infection in

- minor cuts
- scrapes
- burn

**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

**Ask a doctor before use** in case of deep or puncture wounds, animal bites or serious burns

**When using this product** do not use longer than 1 week unless directed by a doctor

**Stop use and ask a doctor 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 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**

- do not use if seal is punctured or is not visible. To open, reverse cap to puncture seal • store at room temperature
- see crimp of tube for Lot No. and Exp. date

**Inactive ingredient** white petrolatum

**Questions or comments ?** call toll free 1-800-645-9833

**PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 1/2 Oz CONTAINER**

Fougera®

NDC 0168-0021-35

**Double Antibiotic Ointment  
(Bacitracin Zinc and Polymyxin B Sulfate Ointment USP)**

Repacked by:  
H.J. Harkins Company, Inc.  
513 Sandydale Drive  
Nipomo, CA 93444

**52959-054-03**
RX Only: #XXXXXXXX #XXX

CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See insert for add'l RX info KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

**BACI.ZINC POLY B.SULF.OINT.**

Lot #: BZO24FO	Compare to: Polysporin OTC
Mfg: FOUGERA	Mfg. NDC: 0168-0021-35
Exp: 03/10	Pill ID: Ointment
Mfg Melville, NY	
Loc.:	

Take as directed by your Doctor or  
See insert for usual dosage information

<b>BACI.ZINC POLY B.SULF.OINT.</b>			
52959-054-03	Qty	1/2oz	
03/10	Lot	BZO24FO	
Polysporin OTC		0168-0021-35	

  

<b>BACI.ZINC POLY B.SULF.OINT.</b>			
52959-054-03	Qty	1/2oz	
03/10	Lot	BZO24FO	
Polysporin OTC		0168-0021-35	

  

<b>BACI.ZINC POLY B.SULF.OINT.</b>			
52959-054-03	Qty	1/2oz	
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Polysporin OTC		0168-0021-35	

  

<b>BACI.ZINC POLY B.SULF.OINT.</b>			
52959-054-03	Qty	1/2oz	
03/10	Lot	BZO24FO	
Polysporin OTC		0168-0021-35	

Repack: HJ Harkins Co., Inc. Nipomo, CA 93444  
 Dispense in tight, child & light-resistant container per USP

<b>BACITRACIN ZINC AND POLYMYXIN B SULFATE</b>			
bacitracin zinc and polymyxin b sulfate ointment			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52959-054(NDC:0168-0021)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Bacitracin Zinc</b> (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I)	Bacitracin Zinc	500 [USP'U] in 1 g
<b>Polymyxin B Sulfate</b> (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)	Polymyxin B Sulfate	1000 [USP'U] in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>petrolatum</b> (UNII: 4T6H12BN9U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-054-03	14.17 g in 1 TUBE		
2	NDC:52959-054-07	28.34 g in 1 TUBE		
3	NDC:52959-054-44	144 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	01/06/2010	

**Labeler** - H.J. Harkins Company, Inc. (147681894)**Establishment**

Name	Address	ID/FEI	Business Operations
Nycomed US Inc.		17449 1316	MANUFACTURE

**Establishment**

Name	Address	ID/FEI	Business Operations
Nycomed US Inc.		043838424	ANALYSIS, MANUFACTURE

Revised: 8/2011

H.J. Harkins Company, Inc.