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.

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 bums

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

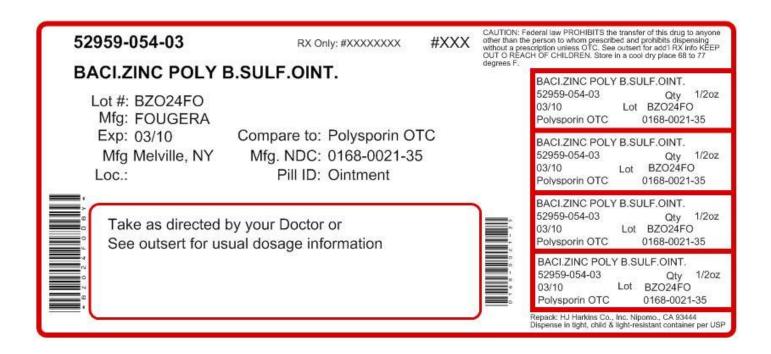
Fougera[®]

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



BACITRACIN ZINC AND POLYMYXIN B SULFATE bacitracin zinc and polymyxin b sulfate ointment Product Information Product Type HUMAN OTC DRUG Route of Administration HUMAN OTC DRUG TOPICAL TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Bacitracin Zinc (UNII: 89 Y4M234ES) (Bacitracin - UNII:58 H6 RWO52I)	Bacitracin Zinc	500 [USP'U] in 1 g	
Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)	Polymyxin B Sulfate	1000 [USP'U] in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
petrolatum (UNII: 4T6H12BN9U)	

P	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.		174491316	MANUFACTURE

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

Revised: 8/2011 H.J. Harkins Company, Inc.