

NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC - neomycin and polymyxin b sulfates and bacitracin zinc 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[®] Triple Antibiotic Ointment
(Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ointment USP)**

Drug Facts

Active ingredients (in each gram)

Neomycin Sulfate (5 mg equivalent to 3.5 mg neomycin base)

Polymyxin B Sulfate (equal to 5,000 polymyxin B units)

Bacitracin Zinc (equal to 400 bacitracin units)

Purpose

Antibiotic

Antibiotic

Antibiotic

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

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 52959-014

**Triple Antibiotic Ointment
(Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ointment USP)**

Repacked by:

H.J. Harkins Company, Inc.
513 Sandysdale Drive
Nipomo, CA

52959-014-05

BACI.NEO.POLY B.SULF.ZINC OINT

Lot #: BP21FO
Mfg: FOUGERA
Exp: 07/10
Mfg Melville, NY
Loc.:

RX Only: #XXXXXXXX #XXX

Compare to: Neosporin OTC
Mfg. NDC: 0168-0012-35
Pill ID: Ointment

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 outsert for add'l RX info KEEP OUT O REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

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

BACI.NEO.POLY B.SULF.ZINC OINT			
52959-014-05	Qty	1/2oz	
07/10	Lot	BP21FO	
Neosporin OTC		0168-0012-35	

BACI.NEO.POLY B.SULF.ZINC OINT			
52959-014-05	Qty	1/2oz	
07/10	Lot	BP21FO	
Neosporin OTC		0168-0012-35	

BACI.NEO.POLY B.SULF.ZINC OINT			
52959-014-05	Qty	1/2oz	
07/10	Lot	BP21FO	
Neosporin OTC		0168-0012-35	

BACI.NEO.POLY B.SULF.ZINC OINT			
52959-014-05	Qty	1/2oz	
07/10	Lot	BP21FO	
Neosporin OTC		0168-0012-35	

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

NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC

neomycin and polymyxin b sulfates and bacitracin zinc ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52959-014(NDC:0168-0012)
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 [USP'U] in 1 g
Neomycin Sulfate (UNII: 057Y626693) (Neomycin - UNII:I16QD7X297)	Neomycin Sulfate	5 mg in 1 g
Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)	Polymyxin B Sulfate	5000 [USP'U] in 1 g

Inactive Ingredients

Ingredient Name	Strength
petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-014-05	14.17 g in 1 TUBE		
2	NDC:52959-014-03	28.34 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)**Registrant** - Nycomed US Inc. (043838424)**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.