

BACITRACIN ZINC - 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.

Bacitracin Zinc Ointment USP

Drug Facts

Active ingredients (in each gram)

Bacitracin Zinc (equal to 500 bacitracin units)

Purpose

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 store at room temperature

Inactive ingredient white petrolatum

E. FOUGERA and CO.

a division of Nycomed US Inc.
MELVILLE, NEW YORK 11747

Repacked by:

H.J. Harkins Company Inc.
Nipomo, CA 93444

52959-113-03

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

BACITRACIN ZINC OINT.

Lot #: BAT98FO
Mfg: NYCOMED
Exp: 11/10 Compare to: OTC
Mfg Melville, NY Mfg. NDC: 0168-0011-31
Loc.: Pill ID: Ointment

BACITRACIN ZINC OINT.
52959-113-03 Qty 1oz
11/10 Lot BAT98FO
OTC 0168-0011-31

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

Repack: HJ Harkins Co., Inc. Nipomo., CA 9344
Dispense in tight, child & light-resistant container per USP

BACITRACIN ZINC

bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52959-113(NDC:0168-0011)
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 [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:52959-113-03	28.34 g in 1 TUBE		
2	NDC:52959-113-15	14.17 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	01/08/2010	

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

Registrant - Nycomed US Inc. (043838424)

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.