

BACITRACIN ZINC- bacitracin zinc ointment
E. FOUGERA & CO., A division of Fougera Pharmaceuticals 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

Active Ingredient (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 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 Number and Exp. Date

Inactive Ingredients

white petrolatum

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

E. FOUGERA & CO.

A division of Fougera Pharmaceuticals Inc.

Melville, NY 11747

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 4 Oz CONTAINER

NDC 0168-0011-04

Fougera®

NET WT 113.4 g (4 Oz)

FOR HOSPITAL USE ONLY

Bacitracin Zinc Ointment USP

First Aid Antibiotic

NDC 0168-0011-04

NET WT 113.4 g (4 Oz)

fougera®

FOR HOSPITAL USE ONLY

Bacitracin Zinc Ointment USP

First Aid Antibiotic

Drug Facts

Active ingredient (in each gram)

Purpose

Bacitracin Zinc (equal to 500 bacitracin units).....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

E. FOUGERA & CO.
A division of
Fougera Pharmaceuticals Inc.
Melville, New York 11747

X4730B R09/11



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 4 Oz Carton

Fougera®

**Bacitracin Zinc
Ointment USP**

First Aid Antibiotic

NDC 0168-0011-04

FOR HOSPITAL USE ONLY

NET WT 113.4 g (4 Oz)



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 1/32 Oz CONTAINER

Fougera®

First Aid Antibiotic

**Bacitracin Zinc
Ointment USP**

Uses: First aid to help prevent infection

in . minor cuts . scrapes . burns

NET WT. 0.9 g (1/32 Oz)

NDC 0168-0111-09

Drug Facts (continued)

Uses: First aid to help prevent infection in • minor cuts • scrapes • burns

Warnings: For external use only. Do not use • in eyes • over large areas of body • if you are allergic to any of the ingredients • longer than 1 week unless directed by a doctor. **Ask a Doctor in case of** • deep puncture wounds • animal bites • serious burns. **Stop use and ask a doctor** • if the condition persists or gets worse • if a rash or 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 (equal to the surface area of the tip of a finger) 1 to 3 times daily • may be covered with a sterile bandage. **Other information:** Store at room temperature. **Inactive ingredient:** Mineral oil and white petrolatum.

E. Fougera & Co., A division of Fougera Pharmaceuticals Inc., Melville, NY 11747

FP5017D R06/13

fougera®

First Aid Antibiotic NET WT 0.9 g (1/32 oz)

**Bacitracin Zinc
Ointment USP**

Drug Facts

Active ingredient (in each gram): Bacitracin Zinc
(equal to 500 bacitracin units) **Purpose:** Antibiotic



This product available in tubes at pharmacy.

foilpac®

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – FOILPAC CARRIER CARTON

NDC 0168-0111-09

Fougera®

Bacitracin Zinc

Ointment USP

First Aid Antibiotic

This product available in tubes at pharmacy.

1 GROSS

NET WT. 0.9 g (1/32 Oz) FOILPACS®

TEAR OFF HERE AND AT COVER FOR EASY ACCESS

Drug Facts

Active ingredient (in each gram)	Purpose
Bacitracin Zinc (equal to 500 bacitracin units)	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 ingredients mineral oil and white petrolatum

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

E. FOUGERA & CO., A division of Fougera Pharmaceuticals Inc., Melville, New York 11747

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R02/15

NDC 0168-0111-09

fougera[®]

**Bacitracin Zinc
Ointment USP**
First Aid Antibiotic

This product available in tubes at pharmacy.

1 GROSS
NET WT 0.9 g (1/32 oz) FOILPACS[®]

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 1 lb jar CONTAINER

Fougera[®]

NDC 0168-0011-16

NET WT 453.6 g (1 lb)

Bacitracin Zinc Ointment USP

First Aid Antibiotic FOR HOSPITAL USE ONLY

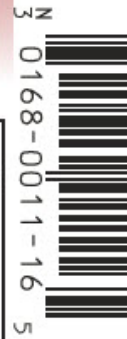
NDC 0168-0011-16

fougera®

NET WT 453.6 g (1 lb)

Bacitracin Zinc Ointment USP

First Aid Antibiotic

LOT NO.
EXP. DATE**Drug Facts****Active ingredient (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

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

E. FOUGERA & CO.

A division of Fougera Pharmaceuticals Inc., Melville, New York 11747

L21116J R08/14

BACITRACIN ZINC

bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0168-0011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	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:0168-0011-35	1 in 1 CARTON		
1		14.17 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0168-0011-31	1 in 1 CARTON		
2		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0168-0011-04	1 in 1 CARTON		
3		113.4 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:0168-0011-16	453.6 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

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

BACITRACIN ZINC

bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0168-0111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	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:0168-0111-09	144 in 1 CARTON		
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

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

Labeler - E. FOUGERA & CO., A division of Fougera Pharmaceuticals Inc. (043838424)

Revised: 8/2014

E. FOUGERA & CO., A division of Fougera Pharmaceuticals Inc.