

DOUBLE ANTIBIOTIC- bacitracin zinc and polymyxin b sulfate 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.

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 store at room temperature

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)

fougera ®		NDC 0168-0021-35
Double Antibiotic Ointment (Bacitracin Zinc and Polymyxin B Sulfate Ointment USP)		
First Aid Antibiotic	NET WT 14.17 g (1/2 Oz)	
Active ingredients (in each gram)	Purpose	
Bacitracin Zinc (equal to 500 bacitracin units)	Antibiotic	
Polymyxin B Sulfate (equal to 10,000 polymyxin B 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		
Inactive ingredient white petrolatum		
E. FOUGERA & CO., A division of Fougera Pharmaceuticals Inc. Melville, New York 11747	U4731B R11/11	 3 0168-0021-35 5

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 1/2 Oz CARTON

NDC 0168-0021-35

Fougera®

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

First Aid Antibiotic



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

NDC 0168-0021-09

Fougera®

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

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

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

Active ingredient: bacitracin - 500 units, polymyxin B - 10,000 units

WARNINGS: For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, see a doctor. Stop use and see a doctor if the condition persists or gets worse, or if a rash or other allergic reaction develops. Do not use if you are allergic to any of the ingredients. Do not use longer than 1 week unless directed by a doctor. **Keep out of the 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. Store at room temperature.

Inactive ingredients: white petrolatum

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

**FP5016B
R11/11**



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – FOILPAC CARRIER CARTON

NDC 0168-0021-09

Fougera®

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

First Aid Antibiotic

This product available in tubes at pharmacy.

1 GROSS

NET WT 0.9 g (1/32 Oz) FOILPACS®

NDC 0168-0021-09

fougera®

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

This product available in tubes at pharmacy.

1 GROSS
NET WT 0.9 g (1/32 Oz) FOILPACS®

Drug Facts

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Bacitracin Zinc (equal to 500 bacitracin units)..... Antibiotic
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E. FOUGERA & CO., A division of Fougera Pharmaceuticals Inc., Melville, New York 11747

FPC4863B
Rt1/11

DOUBLE ANTIBIOTIC

bacitracin zinc and polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0168-0021
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
Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)	Polymyxin B	10000 [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:0168-0021-35	1 in 1 CARTON		
1		14.17 g in 1 TUBE		
2	NDC:0168-0021-31	1 in 1 CARTON		
2		28.35 g in 1 TUBE		
3	NDC:0168-0021-09	1 in 1 CARTON		
3		0.9 g in 1 PACKET		

Marketing Information

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

Labeler - E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. (043838424)

Revised: 2/2013

E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.