

**DOUBLE ANTIBIOTIC- bacitracin zinc and polymyxin b sulfate ointment
Preferred 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

28gr tube - 68788-9488-2

Fougera®

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

First Aid Antibiotic

Double Antibiotic Ointment
Generic for: Polysporin
Each gram contains: Polymyxin B Sulfate (equal to 10,000 polymyxin B units) / Bacitracin Zinc (equal to 500 bacitracin units)

Pkg Size: Exp Date:
Lot#: Batch#:
Ins:
Mfg: E. Fougera & Co., Melville, NY
Prod#:

Warning
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. Keep out of reach of children. Store at room temperature. Do not use if seal is punctured or is not visible.

Directions English
Apply externally _____ times a day.

PhREFERRED Pharmaceuticals, Inc. Anaheim, Ca
The Physician's Solution.

CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed.

Directions Espanol:
Aplique externamente _____ veces al dia.

Double Antibiotic Ointment Qty: Ins: Lot#: Bat#: Prod# (NDC):

Double Antibiotic Ointment Qty: Ins: Lot#: Bat#: Prod# (NDC):

Double Antibiotic Ointment Qty: Ins: Lot#: Bat#: Prod# (NDC):

Double Antibiotic Ointment Qty: Ins: Lot#: Bat#: Prod# (NDC):

Log
Chart
Billing
Patient

DOUBLE ANTIBIOTIC			
bacitracin zinc and polymyxin b sulfate ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-9488(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:68788-9488-2	1 in 1 CARTON		
1		28.35 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	05/20/2014	

Labeler - Preferred Pharmaceuticals, Inc. (791119022)**Registrant** - Preferred Pharmaceuticals, Inc. (791119022)**Establishment**

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc.		791119022	RELABEL(68788-9488)

Revised: 5/2014

Preferred Pharmaceuticals, Inc.