

**DOUBLE ANTIBIOTIC- bacitracin zinc and polymyxin b sulfate ointment**  
**Rebel Distributors Corp**

*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.*

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**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

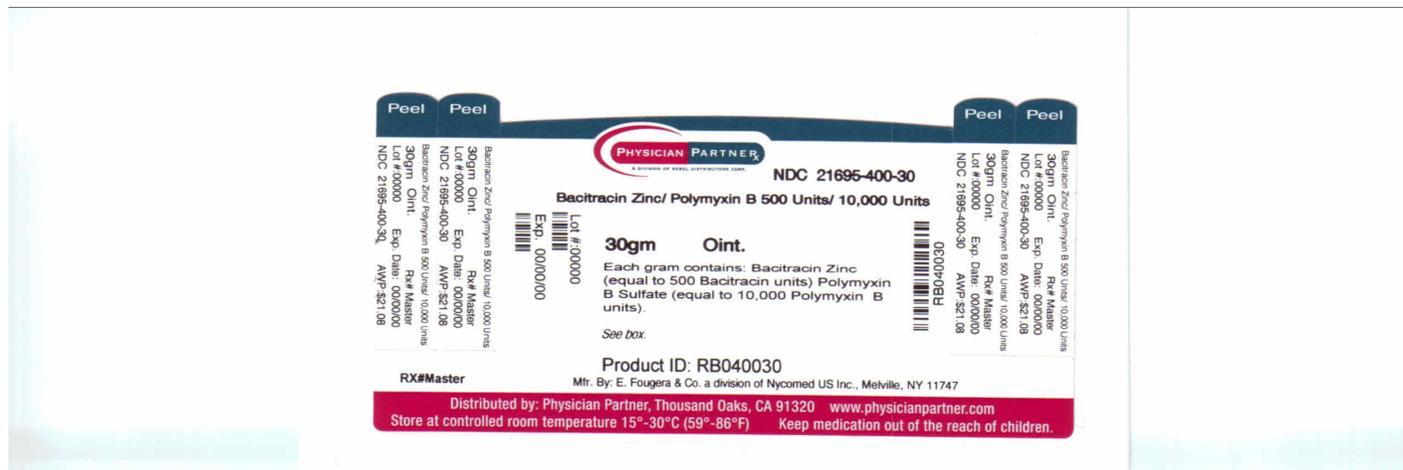
- do not use if seal is punctured or is not visible. To open, reverse cap to puncture seal • store at room temperature
- see crimp of tube for Lot No. and Exp. date

**Inactive ingredient** white petrolatum

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

Repackaged by: Rebel Distributors Corp, Thousand Oaks, CA 91320

### PRINCIPAL DISPLAY PANEL



## DOUBLE ANTIBIOTIC

bacitracin zinc and polymyxin b sulfate ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21695-400(NDC:0168-0021)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Bacitracin Zinc</b> (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I)	Bacitracin Zinc	500 [USP'U] in 1 g
<b>Polymyxin B Sulfate</b> (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)	Polymyxin B Sulfate	1000 [USP'U] in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>petrolatum</b> (UNII: 4T6H12BN9U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:21695-400-30	1 in 1 CARTON		
1		30 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** - Rebel Distributors Corp (118802834)

## Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011

Rebel Distributors Corp