

**BACITRACIN ZINC- bacitracin zinc and polymyxin b sulfate ointment**  
**STRATUS 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.*

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**BACITRACIN ZINC**

***Drug Facts***

<b><i>Active ingredient (in each gram)</i></b>	<b><i>Purpose</i></b>
Bacitracin zinc 500 units	First aid antibiotic
Polymyxin B 10,000 units	First aid 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

**Allergy alert**

- do not use if allergic to any of the ingredients

**When using this product**

- do not use longer than one week unless directed by doctor

**Ask a doctor before use if you have**

- deep or puncture wounds
- animal bites
- serious burns

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Stop use and ask a doctor if**

- condition persists or gets worse
- a rash or other allergic reaction develops

**Directions**

- Clean the affected area

- Apply a small amount of this product on the area 1 to 3 times
- May be covered with a sterile bandage

**Other information**

- Store at room temperature
- Before using any medication, read all label directions.

**Inactive ingredient**

White petrolatum

**Questions or comments?**

Call toll-free 1-800-442-7882

**Distributed by:** Stratus Pharmaceuticals Inc., 12379 SW 130th Street, Miami, Florida 33186

**PRINCIPAL DISPLAY PANEL - 0.9 g Packet Box**

NDC 58980-012-01

STRATUSCARE  
**Double Antibiotic  
Ointment**

(Bacitracin Zinc and  
Polymyxin B Sulfate Ointment USP)

***First Aid Antibiotic***

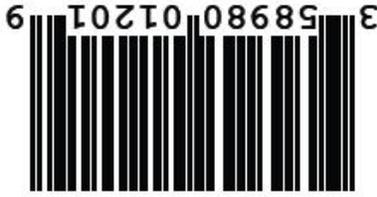
*Distributed by:*

**STRATUS**  
PHARMACEUTICALS INC

**1 GROSS**

Net Wt. 0.9g (1/32 oz) PACKETTES

STRATUS  
PHARMACEUTICALS INC



JD-0488-B-2016-01

1 GROSS  
Net Wt. 0.9g (1/32 oz) PACKETTES

PHARMACEUTICALS INC  
STRATUS  
Distributed by

First Aid Antibiotic

(Bacitracin Zinc and Polymyxin B Sulfate Ointment USP)

Double Antibiotic Ointment

STRATUSCARE

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Double Antibiotic Ointment

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First Aid Antibiotic

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PHARMACEUTICALS INC

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STRATUS  
PHARMACEUTICALS INC

TEAR OFF HERE AND AT COVER FOR EASY ACCESS

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## BACITRACIN ZINC

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### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58980-012
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6RWO52I)	BACITRACIN	500 [USP'U] in 1 g
POLYMYXIN B SULFATE (UNII: 19 371312D4) (POLYMYXIN B - UNII:J2VZ07J96 K)	POLYMYXIN B	10000 [USP'U] in 1 g

### Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

**Product Characteristics**

<b>Color</b>	WHITE (OFF WHITE)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58980-012-01	144 in 1 BOX	09/15/2017	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:58980-012-05	1 in 1 BOX	02/08/2021	
2		14.2 g in 1 TUBE; 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	09/15/2017	

**Labeler** - STRATUS PHARMACEUTICALS INC (789001641)**Establishment**

Name	Address	ID/FEI	Business Operations
TARMAC PRODUCTS INC		059890491	MANUFACTURE(58980-012) , LABEL(58980-012) , PACK(58980-012)

Revised: 2/2021

STRATUS PHARMACEUTICALS INC