

TRIPLE ANTIBIOTIC PLUS PAIN RELIEF- bacitracin zinc, neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride ointment

Phoenix Global Supply Group, 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.

**Triple Antibiotic
Ointment + Pain Relief**

Drug Facts

<i>Active ingredients (each gram contains)</i>	<i>Purpose</i>
Bacitracin zinc 500 units	First aid antibiotic
Neomycin sulfate 3.5 mg	First aid antibiotic
Polymyxin B sulfate 10,000 units	First aid antibiotic
Pramoxine HCl 10 mg	External analgesic

Uses

first aid to help prevent infection and for the temporary relief of pain or discomfort 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 if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition persists or gets worse
- condition persists for more than 7 days
- condition clears up and occurs again within a few days
- 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

- adults and children 2 years of age and older:

- 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
- children under 2 years of age: consult a doctor

Other information

- To open: unscrew cap, pull tab to remove foil seal.
- store at 20°-25°C (68°-77°F)
- See carton or tube crimp for lot number and expiration date.

Inactive ingredient

white petrolatum

Questions?

Call **1-877-745-6888**

Distributed by:

Phoenix Global Supply Group, Inc.

White Plains, NY 10604

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

Triple Antibiotic

Ointment + Pain Relief

Bacitracin Zinc • Neomycin Sulfate • Polymyxin B Sulfate • Pramoxine HCl

First Aid Antibiotic / Pain Relieving Ointment

Maximum Strength

NET WT 1 oz (28.4 g)

Compare to the active ingredients in NEOSPORIN® + Pain Relief*

Maximum Strength

HELPS PREVENT INFECTION of MINOR CUTS, SCRAPES, AND BURNS

First Aid Antibiotic / Pain Relieving Ointment

Triple Antibiotic Ointment + Pain Relief

Bacitracin Zinc • Neomycin Sulfate • Polymyxin B Sulfate • Pramoxine HCl

CN100005-0
0610-0

Triple Antibiotic Ointment + Pain Relief

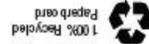
Bacitracin Zinc • Neomycin Sulfate • Polymyxin B Sulfate • Pramoxine HCl

First Aid Antibiotic / Pain Relieving Ointment

Maximum Strength

NET WT 1 oz (28.4 g)

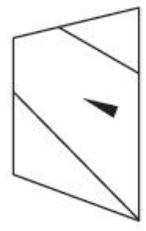
Triple Antibiotic
Ointment + Pain Relief
Bacitracin Zinc • Neomycin Sulfate
Polymyxin B Sulfate
Pramoxine HCl



PHOENIX
Distributed by:
Pharmacia Group, Inc.
White Plains, NY 10504
Made in U.S.A.

*This product is not manufactured or distributed by Johnson & Johnson Corporation, or its affiliates, owner of the registered trademark Neosporin® + Pain Relief.

<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> condition persists or gets worse condition recurs within a few days condition recurs again within a few days rash or other allergic reaction develops <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> adults and children 2 years of age and older: <ul style="list-style-type: none"> 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 children under 2 years of age: consult a doctor <p>Other information</p> <ul style="list-style-type: none"> to open: unscrew cap, pull tab to remove bill seal. store at 20°-25°C (68°-77°F) See carton or tube crimp for lot number and expiration date. <p>Inactive ingredient white petrolatum</p> <p>Questions? Call 1-877-745-6888</p>	<p>Drug Facts</p> <p>Active ingredients (each gram contains)</p> <p>Bacitracin zinc 500 units; First aid antibiotic</p> <p>Neomycin sulfate 3.5 mg; First aid antibiotic</p> <p>Polymyxin B sulfate 10,000 units; First aid antibiotic</p> <p>Pramoxine HCl 10 mg; External analgesic</p> <p>Uses First aid to help prevent infection and for the temporary relief of pain or discomfort in minor:</p> <ul style="list-style-type: none"> cuts scrapes burns <p>Warnings For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> in the eyes on large areas of the body if you are allergic to any of the ingredients Ask a doctor before use if you have deep or puncture wounds animal bites serious burns
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TRIPLE ANTIBIOTIC PLUS PAIN RELIEF

bacitracin zinc, neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52426-120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Bacitracin Zinc (UNII: 89Y4M234ES) (Bacitracin Zinc - UNII:89Y4M234ES)	Bacitracin Zinc	500 [iU] in 1 g
Neomycin Sulfate (UNII: 057Y626693) (Neomycin - UNII:I16QD7X297)	Neomycin Sulfate	3.5 mg in 1 g
Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)	Polymyxin B Sulfate	10000 [iU] in 1 g
Pramoxine Hydrochloride (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine Hydrochloride	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52426-120-05	1 in 1 CARTON		
1		14.2 g in 1 TUBE		
2	NDC:52426-120-06	1 in 1 CARTON		
2		28.4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333B	09/23/2010	

Labeler - Phoenix Global Supply Group, Inc (843189908)

Establishment

Name	Address	ID/FEI	Business Operations
SGS Life Science Services		093840643	ANALYSIS

Establishment

Name	Address	ID/FEI	Business Operations
Axellia Pharmaceuticals ApS		305814345	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Pharmacia and UpJohn Company		829076566	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
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Syn-Tech Chem. & Pharm. Co., Ltd.		656002532	API MANUFACTURE
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Establishment

Name	Address	ID/FEI	Business Operations
Axellia Pharmaceuticals AS		56 18 16 174	MANUFACTURE

Revised: 9/2010

Phoenix Global Supply Group, Inc