

ANTIBIOTIC PLUS PAIN RELIEF- neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride cream

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.

**Antibiotic
Cream + Pain Relief**

Drug Facts

<i>Active ingredients (each gram contains)</i>	<i>Purpose</i>
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 ingredients

emulsifying wax, methylparaben, mineral oil, propylene glycol, purified water, 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

Antibiotic

Cream + Pain Relief

Neomycin Sulfate • Polymyxin B Sulfate • Pramoxine HCl

First Aid Antibiotic / Pain Relieving Cream

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 Cream

CMD0007-0
07-10-0

Antibiotic Cream + Pain Relief

Neomycin Sulfate • Polymyxin B Sulfate • Pramoxine HCl

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Maximum Strength

NET WT 1 oz (28.4 g)

Antibiotic
Cream + Pain Relief
Neomycin Sulfate • Polymyxin B Sulfate
Pramoxine HCl



100% Recycled Paperboard
PHOENIX
Distributed by
Pharmacia Corporation
The Plains, NY 10604
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

Drug Facts (continued)

Directions

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Drug Facts

Active Ingredients (each gram contains)

Neomycin sulfate 35 mg.....First aid antibiotic
 Polymyxin B sulfate 10,000 units.....First aid antibiotic
 Pramoxine HCl 10 mg.....External analgesic

Purpose

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52426-220
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
petrolatum (UNII: 4T6H12BN9U)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52426-220-05	1 in 1 CARTON		
1		14.2 g in 1 TUBE		
2	NDC:52426-220-06	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		3058 14345	MANUFACTURE

Establishment

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

Establishment

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

Revised: 9/2010

Phoenix Global Supply Group, Inc.