TOPCARE ANTIBIOTIC- neomycin, polymyxin b, pramoxine hydrochloride cream Topco Associates LLC

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.

Topco Associates LLC. Antibiotic Cream Drug Facts

Active ingredients (in each gram)

Neomycin sulfate equivalent to 3.5 mg of neomycin base Polymyxin B 10,000 units as polymyxin B sulfate Pramoxine HCl 10 mg

Purpose

First aid antibiotic

External analgesic

Uses

first aid to help prevent infection and for temporary relief of pain or discomfort in minor:

- cuts
- scrapes
- burns

Warnings

For external use only.

Do not use

- if you are allergic to any of the ingredients
- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- you need to use longer than 1 week
- condition persists or gets worse
- symptoms persist for more than 1 week, or clear up and occur again within a few days
- 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. (1-800-222-1222)

Directions

- adults and children 2 years of age or 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: ask a doctor

Other information

• store at 20°-25°C (68°-77°F)

Inactive ingredients

emulsifying wax, methylparaben, mineral oil, poloxamer 188, propylene glycol, purified water, white petrolatum

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

COMPARE TO NEOSPORIN® + PAIN RELIEF ACTIVE INGREDIENTS

First Aid Antibiotic & Pain Relieving Cream

Helps Prevent Infection in Minor Cuts, Scrapes & Burns

Maximum Strength

MAXIMUM STRENGTH

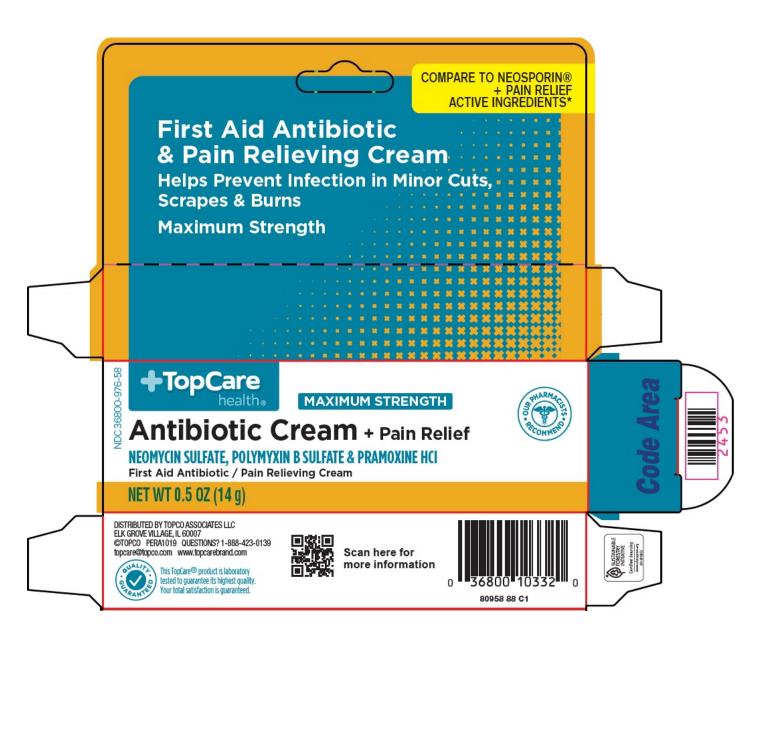
OUR PHARMACISTS RECOMMEND

Antibiotic Cream + Pain Relief

NEOMYCIN SULFATE, POLYMYXIN B SULFATE & PRAMOXINE HCl

First Aid Antibiotic / Pain Relieving Cream

NET WT 0.5 OZ (14 g)







Purpose

Antibiotic Cream

+ Pain Relief

*This product is not affliated with, manufactured by, or produced by the makers of Neosporh®.

Drug Facts

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■ cuts ■ scrapes ■ burns

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Drug Facts (continued)

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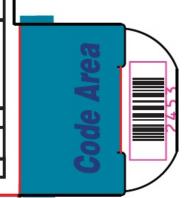
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Questions or comments? 1-888-423-0139



TOPCARE ANTIBIOTIC

neomycin, polymyxin b, pramoxine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-976
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Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 [USP'U] in 1 g
PRAMO XINE HYDRO CHLO RIDE (UNII: 88AYB867L5) (PRAMO XINE - UNII: 068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
METHYLPARABEN (UNII: A2I8C7HI9T)		
MINERAL OIL (UNII: T5L8T28FGP)		
POLOXAMER 188 (UNII: LQA7B6G8JG)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
PETROLATUM (UNII: 4T6H12BN9U)		

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

I	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:36800-976-58	1 in 1 CARTON	04/03/2020	
	1	14 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	04/03/2020	

Labeler - Topco Associates LLC (006935977)

Revised: 4/2020 Topco Associates LLC