

TOPCARE ANTIBIOTIC PLUS PAIN RELIEF- neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride cream
Topco Associates LLC

TopCare®
Antibiotic Plus 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 hydrochloride 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
- you need to use longer than 1 week
- 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.

Directions

Adults and children 2 years of age and older:

- clean the affected area and dry thoroughly
- 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° to 25°C (68° to 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 **1-888-423-0139**

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE,
IL 60007

PRINCIPAL DISPLAY PANEL - 14.2 g Tube Carton

NDC 36800-381-01

TopCare®
health™

MAXIMUM STRENGTH

Antibiotic Cream + Pain Relief

NEOMYCIN SULFATE, POLYMYXIN B SULFATE & PRAMOXINE HCL

• OUR PHARMACISTS
RECOMMEND •

NET WT 0.5 OZ (14.2 g)

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-381
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-381-01	1 in 1 CARTON	03/21/2012	
1		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 Drug	M017	03/21/2012	

Labeler - Topco Associates LLC (006935977)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(36800-381)

