TOPCARE ANTIBIOTIC PLUS PAIN RELIEF- neomycin sulfate, polymyxin b sulfate, and 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.

TopCare®
Antibiotic Plus Pain Relief

Drug Facts

Active ingredients (each gram contains)	*Purpose*
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)

TOPCARE ANTIBIOTIC PLUS PAIN RELIEF

neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride cream

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 FINAL	part333B	03/21/2012	

Labeler - Topco Associates LLC (006935977)

Registrant - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(36800-381)

Revised: 3/2019 Topco Associates LLC