TOPCARE TRIPLE ANTIBIOTIC PLUS PAIN RELIEF- bacitracin zinc, neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride ointment 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_® Triple Antibiotic Plus Pain Relief

Drug Facts

Active ingredients (in each gram)	Purpose
Bacitracin zinc USP 500 units	First aid antibiotic
Neomycin sulfate USP 3.5 mg	First aid antibiotic
Polymyxin B sulfate USP 10,000 units	First aid antibiotic
Pramoxine HCl USP 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

- if you are allergic to any of the ingredients
- in the eves
- 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.

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: ask a doctor

Other information

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

Inactive ingredient

white petrolatum

Questions?

Call 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

 $TopCare_{\mathbb{R}} \\ health_{^{TM}}$

NDC 36800-056-24

MAXIMUM STRENGTH

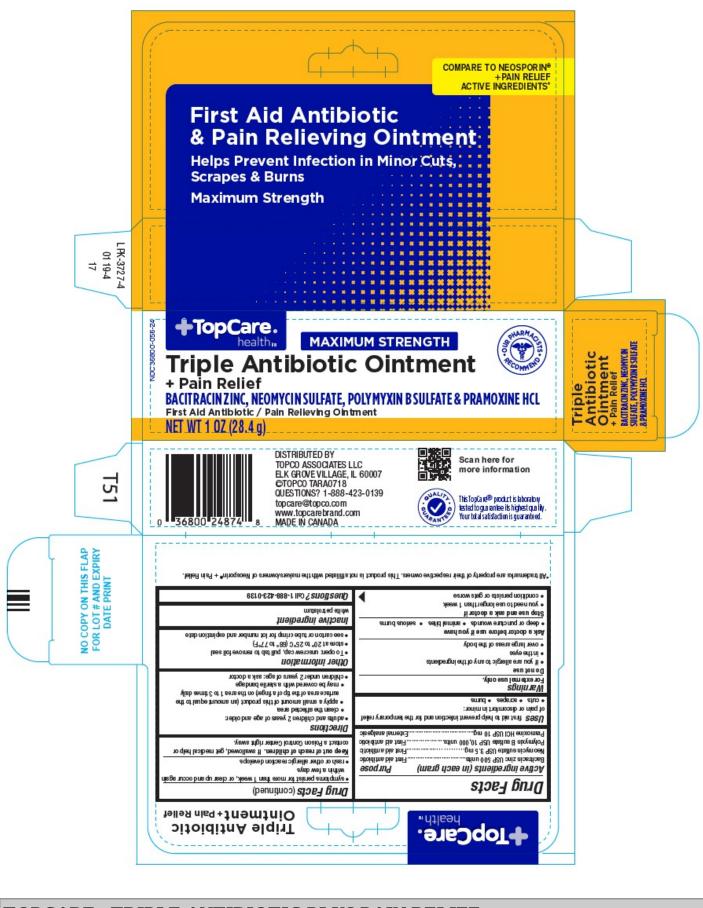
Triple Antibiotic Ointment

+ Pain Relief

BACITRACIN ZINC, NEOMYCIN SULFATE, POLYMYXIN B SULFATE & PRAMOXINE HCL First Aid Antibiotic / Pain Relieving Ointment

• OUR PHARMACISTS RECOMMEND •

NET WT 1 OZ (28.4 g)



TOPCARE 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:36800-056
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Bacitracin zinc (UNII: 89 Y4M234ES) (Bacitracin - UNII:58 H6 RWO 52I)	Bacitracin	500 [iU] in 1 g	
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
petrolatum (UNII: 4T6H12BN9U)	

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:36800-056-24	1 in 1 CARTON	03/31/2012	
	1	28.4 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	03/31/2012	

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(36800-056)	

Revised: 4/2019 Topco Associates LLC