# SHOPKO TRIPLE ANTIBIOTIC PLUS PAIN RELIEF- bacitracin zinc, neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride ointment Shopko Stores Operating Co., 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.

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# $\textbf{Shopko}^{\text{(R)}}$

## Triple Antibiotic plus Pain Relief

#### **Drug Facts**

Active ingredients (each gram contains)	Purpose
Bacitracin zinc 500 units	First aid antibiotic
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 eves
- 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
- 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 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

- 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 1-866-923-4914

#### PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

**SHOPKO**®

NDC 37012-027-02

Maximum Strength

#### **Triple Antibiotic Ointment+Pain Relief**

Bacitracin Zinc • Neomycin Sulfate • Polymyxin B Sulfate • Pramoxine Hydrochloride

# First Aid Antibiotic / Pain Relieving Ointment

NET WT 1 OZ (28.4 g)



#### SHOPKO 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:37012-027
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			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:37012-027-01	1 in 1 CARTON		
1	14.2 g in 1 TUBE		
2 NDC:37012-027-02	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	0 3/3 1/2 0 12	

# Labeler - Shopko Stores Operating Co., LLC (023252638)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(37012-027)

Revised: 4/2014