

WESTERN FAMILY TRIPLE ANTIBIOTIC PLUS PAIN RELIEF- bacitracin zinc, neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride ointment
Western Family Foods Inc

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.

Western Family®
Triple Antibiotic plus Pain Relief

Drug Facts

<i>Active ingredients (each gram contains)</i>	<i>Purpose</i>
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	Topical 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
- longer than 1 week

Ask a doctor before use

- on deep or puncture wounds, animal bites, or serious burns

Stop use and ask a doctor if

- condition gets worse
- condition persists for more than 7 days
- condition clears up and occurs 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: consult a doctor

Other information

- To open: unscrew cap, pull tab to remove foil seal
- store at room temperature
- see carton or tube crimp for lot number and expiration date

Inactive ingredient

white petrolatum

Questions?

Call 1-866-923-4914

Distributed By:

Western Family Foods, Inc.

P.O. Box 4057, Portland, OR 97208

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

Triple Antibiotic

(Bacitracin Zinc-Neomycin Sulfate

Polymyxin B Sulfate-Pramoxine HCL)

OINTMENT+ PAIN RELIEF

NET WT 1 OZ

(28g)

First Aid Antibiotic /Topical Pain Reliever

Maximum Strength

COMPARE TO THE ACTIVE INGREDIENTS OF NEOSPORIN® PLUS*



**Prevents Infection
AND
Soothes Painful
Cuts, Scrapes & Burns**

Our product combines a topical pain reliever with three, maximum strength antibiotics widely recommended by physicians.

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Triple Antibiotic OINTMENT + PAIN RELIEF

(Bacitracin Zinc-Neomycin Sulfate Polymyxin B Sulfate-Pramoxine HCl)

NET WT 1 OZ (28g)

First Aid Antibiotic / Topical Pain Reliever



Triple Antibiotic OINTMENT + PAIN RELIEF



0609-3

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PO. Box 4167, Portland, OR 97208
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Drug Facts (continued)
Other information
• To open, unscrew cap, pull tab to remove foil seal
• Store at room temperature
• See carton or tube crimp for lot number and expiration date
Inactive ingredient white petrolatum
Questions? Call 1-888-823-4914

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-504
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Bacitracin zinc (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I)	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:55312-504-02	1 in 1 CARTON		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333B	03/31/2012	

Labeler - Western Family Foods Inc (192166072)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(55312-504)

Revised: 3/2013

Western Family Foods Inc