

SAFeway ANTIBIOTIC PLUS PAIN RELIEF- neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride cream

Safeway 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.

Safeway™

Antibiotic Plus Pain Relief

Drug Facts

Active ingredients (each gram contains)	Purpose
Neomycin sulfate 3.5mg	First aid antibiotic
Polymyxin B sulfate 10,000 units	First aid antibiotic
Pramoxine hydrochloride 10mg	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

- store at controlled room temperature
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

emulsifying wax, methylparaben, mineral oil, propylene glycol, purified water, white petrolatum

DISTRIBUTED BY SAFEWAY INC.

P.O. BOX 99

PLEASANTON, CA 94566-0009

1-888-SAFEWAY

PRINCIPAL DISPLAY PANEL - 14.2g Tube Carton

Maximum Strength

NDC 21130-076-01

Antibiotic Cream + Pain Relief

• **Neomycin Sulfate** • **Polymyxin B Sulfate** • **Pramoxine HCl**

NET WT ½ OZ (14.2g)

SAFEWAY™

Maximum Strength

Antibiotic Cream + Pain Relief

First Aid Antibiotic / Pain Relieving Cream

- Neomycin Sulfate
- Polymyxin B Sulfate
- Pramoxine HCl

NET WT 1/2 OZ (14.2g)

SAFeway 

NDC 21130-076-01
Compare to the active ingredients in Neosporin® Plus Pain Relief *



Helps Prevent Infection in Minor Cuts, Scrapes, and Burns Plus Maximum Strength Pain Relief

LPK-5815-1
0509-1
M475

T 27

Maximum Strength

Antibiotic Cream + Pain Relief

• Neomycin Sulfate • Polymyxin B Sulfate • Pramoxine HCl

NET WT 1/2 OZ (14.2g)

SAFeway 

NDC 21130-076-01

Antibiotic Cream + Pain Relief



RD 09081

Drug Facts (continued)

Other information

- store at controlled room temperature
- see carton or tube crimp for lot number and expiration date

Inactive ingredients emulsifying wax, methylparaben, mineral oil, propylene glycol, purified water, white petrolatum.

DISTRIBUTED BY SAFEWAY INC.
P.O. BOX 99
PLEASANTON, CA 94566-0099
1-888-SAFEWAY
www.safeway.com
MADE IN CANADA
S2840



Drug Facts (each gram contains)

Neomycin sulfate 3.5mg, Polymyxin B sulfate 10,000 units, Pramoxine hydrochloride 10mg, Topical analgesic

Purpose First aid antibiotic distributors of Neosporin® Plus.

Uses First aid to help prevent infection and for the temporary relief of pain or discomfort in minor cuts, scrapes, and 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. Children under 2 years of age: Consult a doctor. May be covered with a sterile bandage.

Antibiotic Cream + Pain Relief
First Aid Antibiotic / Pain Relieving Cream

SAFeway ANTIBIOTIC PLUS PAIN RELIEF
neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-076
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: 059QF0K00R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-076-01	1 in 1 CARTON		
1		14.2 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	03/21/2012	

Labeler - Safeway Inc (009137209)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(21130-076)

Revised: 3/2013

Safeway Inc