# EQUALINE ANTIBIOTIC PLUS PAIN RELIEF FOR KIDS- neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride cream Supervalu 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.

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equaline<sup>®</sup> antibiotic plus pain relief for kids

#### **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: consult 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 1-877-932-7948

DISTRIBUTED BY SUPERVALU INC. EDEN PRAIRIE, MN 55344 USA

## PRINCIPAL DISPLAY PANEL - 14.2g Tube Carton

**equaline**®

compare to the active ingredients in Neosporin<sup>®</sup> + Pain Relief\*

NDC 41163-076-11 maximum strength

antibiotic cream

+ pain relief for kids

neomycin sulfate-polymyxin B sulfate-pramoxine HCl first aid antibiotic/pain relieving cream

**NET WT** 

1/2 OZ (14.2g)



# **EQUALINE ANTIBIOTIC PLUS PAIN RELIEF FOR KIDS**

neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-076
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Neomycin sulfate (UNII: 057Y626693) (Neomycin - UNII:116QD7X297)	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)	Pramo xine hydro chlo ride	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)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-076-11	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 - Supervalu Inc (006961411)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(41163-076)	

Revised: 3/2013 Supervalu Inc