CAREONE ANTIBIOTIC PLUS PAIN RELIEF- neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride cream
American Sales Company

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.

CAREONE™
Antibiotic Plus Pain Relief

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	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
AMERICAN SALES COMPANY
4201 WALDEN AVENUE
LANCASTER, NY 14086

PRINCIPAL DISPLAY PANEL - 14.2 g Tube Carton

CAREONE™

MAXIMUM STRENGTH
ANTIBIOTIC CREAM + PAIN RELIEF
Neomycin Sulfate • Polymyxin B Sulfate • Pramoxine HCl

FIRST AID ANTIBIOTIC / PAIN RELIEVING CREAM

NET WT 1/2 oz

(14.2 g)

Compare to the active ingredients in Neosporin® Plus Pain Relief *

CareOne™

MAXIMUM STRENGTH

ANTIBIOTIC CREAM + PAIN RELIEF

Neomycin Sulfate • Polymyxin B Sulfate • Pramoxine HCl

FIRST AID ANTIBIOTIC / PAIN RELIEVING CREAM

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

CareOne™

MAXIMUM STRENGTH

ANTIBIOTIC CREAM + PAIN RELIEF

Neomycin Sulfate • Polymyxin B Sulfate • Pramoxine HCl

FIRST AID ANTIBIOTIC / PAIN RELIEVING CREAM

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Drug Facts (continued)

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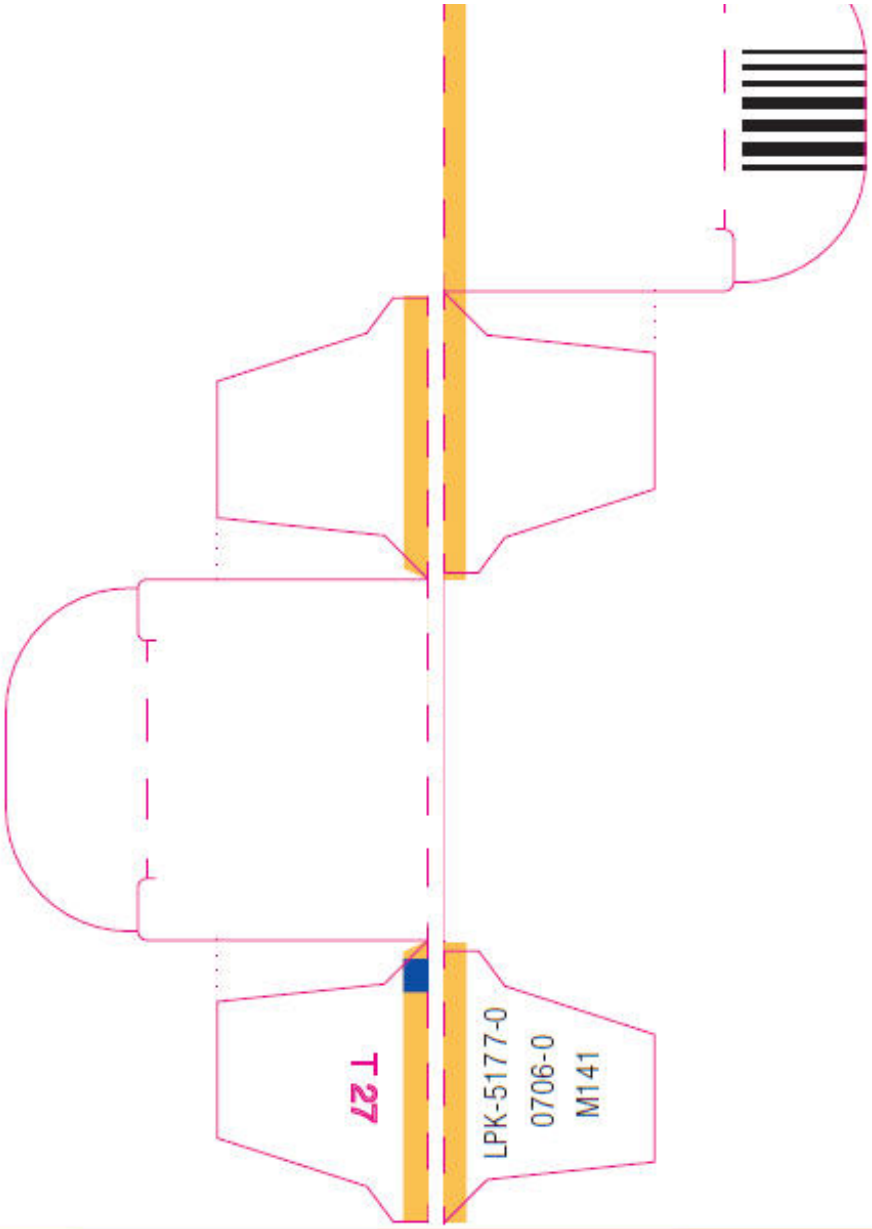
www.carel.info



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*This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Neosporin® Plus.

CAREONE ANTIBIOTIC PLUS PAIN RELIEF

neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-076
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: 059QF0KO0R)	
petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-076-01	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 - American Sales Company (809183973)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(41520-076)