PUBLIX ANTIBIOTIC PLUS PAIN RELIEF- neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride cream Publix Super Markets 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.

Publix antibioticcream 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

- To open: unscrew cap, pull tab to remove foil seal
- 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 PUBLIX SUPER MARKETS, INC. 3300 PUBLIX CORPORATE PARKWAY LAKELAND, FL 33811

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

Publix antibioticcream+

PAIN RELIEF

NEOMYCIN SULFATE • POLYMYXIN B SULFATE • PRAMOXINE HCI

FIRST AID ANTIBIOTIC CREAM PLUS PAIN RELIEVER

NET WT 1 OZ (28.4g)



PUBLIX ANTIBIOTIC PLUS PAIN RELIEF

neomycin sulfate, polymyxin b sulfate, and pramoxine hydrochloride cream

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41415-076 |
|-------------------------|----------------|--------------------|---------------|
| Pouts of Administration | TORICAL | | |

| 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) | | | |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:41415-076- 75 | 1 in 1 CARTON | 03/21/2012 | |
| 1 | | 28.4 g in 1 TUBE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|------------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH FINAL | part333B | 03/21/2012 | |
| | | | |

Labeler - Publix Super Markets Inc (006922009)

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

| Establishment | | | | |
|---------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Taro Pharmaceuticals Inc. | | 206263295 | MANUFACTURE(41415-076) | |

Revised: 12/2021 Publix Super Markets Inc