

**PUBLIX CALAMINE MEDICATED- zinc acetate and pramoxine hydrochloride lotion**

**Publix**

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**Publix Calamine Medicated Lotion**

**Drug Facts**

**Active Ingredients**

Zinc Acetate 8%

Pramoxine HCl 1%

**Purpose**

Skin Protectant

External analgesic

**Uses**

Dries the oozing and weeping, and temporarily relieves pain and itching of poison ivy, oak, and sumac or other skin irritations.

**Warnings**

For external use only. Use only as directed.

When using this product. Avoid contact with eyes and mucous membranes.

Ask a doctor before using on children 2 years of age.

**Stop use and ask a doctor if**

condition worsens. Symptoms last for more than 7 days or clear up and occur again within a few days.

**Keep out of reach of children.**

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

**Directions**

Adults and children 2 yr. of age and older. Shake well before using. Cleanse the skin with soap and water and let dry. Apply to the affected area using cotton or soft cloth, not

more than 3 to 4 times daily as needed for comfort.

Children under 2 yrs. of age. Consult a doctor before use.

## Inactive Ingredients

SD Alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methycelulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben and Purified Water.

## Other information

Store at room temperature 15-30C (59-86F)

## Label

**Publix**  
**calamine**  
MEDICATED LOTION

skin protectant • external analgesic

For the temporary relief of pain and itching associated with minor skin irritations.

Compare to the active ingredient of Caladryl Lotion®\*

NET WT. 6 FLOZ (177 mL)

|                                       |  |
|---------------------------------------|--|
| <b>Drug Facts</b>                     | <b>Purpose</b>   |
| <b>Active ingredients</b>             | Calamine 8%.....Skin protectant  |
|                                       | Pramoxine HCl 1%.....External analgesic  |
| <b>Use</b>                            | Dries the oozing and weeping, and temporarily relieves pain and itching of poison ivy, oak, and sumac or other minor skin irritations.   |
| <b>Warnings</b>                       | <b>For External Use Only.</b> Use only as directed.  |
|                                       | ■ <b>When using this product</b> avoid contact with eyes.  |
| <b>Stop use and ask a doctor if</b>   | ■ condition worsens ■ symptoms last for more than 7 days or clear up and occur again within a few days.  |
| <b>Keep out of reach of children.</b> | In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.  |
| <b>Directions</b>                     | ■ <b>Adults and children 2 yrs. of age and older:</b> Shake well before using. Cleanse the skin with soap and water and let dry. Apply to the affected area using cotton or soft cloth not more than 3 to 4 times daily as needed for comfort. |
|                                       | ■ <b>Children under 2 yrs. of age:</b> Consult a doctor.   |
| <b>Other information</b>              | ■ Store at room temperature 15° - 30°C (59° - 85°F).   |
| <b>Inactive ingredients</b>           | SD Alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hypromellose, Methylparaben, Polysorbate 80, Propylene Glycol Propylparaben and Purified Water.   |

\* This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Caladryl®.  
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## PUBLIX CALAMINE MEDICATED

zinc acetate and pramoxine hydrochloride lotion

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:41415-420 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength          | Strength         |
|---|----------------------------|------------------|
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)            | ZINC CATION                | 80 mg<br>in 1 mL |
| <b>PRAMOXINE HYDROCHLORIDE</b> (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056) | PRAMOXINE<br>HYDROCHLORIDE | 10 mg<br>in 1 mL |

## Inactive Ingredients

| Ingredient Name                             | Strength |
|---|----------|
| <b>ALCOHOL</b> (UNII: 3K9958V90M)           |          |
| <b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941) |          |
| <b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4) |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)          |          |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)     |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)    |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)  |          |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)     |          |
| <b>WATER</b> (UNII: 059QF0KO0R)             |          |

## Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:41415-420-96 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/26/2017           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M016                                     | 03/25/1998           |                    |

**Labeler** - Publix (006922009)

**Registrant** - Pharma Nobis, LLC (118564114)

## Establishment

| Name              | Address | ID/FEI    | Business Operations   |
|-------------------|---------|-----------|---|
| Pharma Nobis, LLC |         | 118564114 | analysis(41415-420) , manufacture(41415-420) , pack(41415-420) , label(41415-420) |

Revised: 12/2023

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