

**CALAMINE PHENOLATED TOPICAL SUSPENSION- calamine and zinc oxide and phenol lotion**  
**Pharma Nobis, LLC**

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**Private Label Calamine Phenolated Topical Suspension, USP**

**Drug Facts**

**Active Ingredient**

Calamine 8%

**Purpose**

Skin Protectant

**Active Ingredient**

Zinc Oxide 8%

**Purpose**

Skin Protectant

**Active Ingredient**

Liquefied Phenol

**Purpose**

Topical Analgesic

**Uses**

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

**Warnings**

- **For external use only.** Use only as directed.
- **Avoid contact with** eyes and mucous membranes.
- **Do not apply to** large areas of the body or in large quantities, particularly over raw or blistered areas.
- **If applied to** fingers or toes do not bandage.

**Ask a doctor**

before using on children under 2 years of age.

When using this product. Discontinue use if condition worsen or does not improve within 7 days and consult a doctor.

**Keep out of reach of children.**

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

**directions (Shake well before using)**

**Adult and children 2 years of age and older:** Cleanse the skin with soap and water and let dry before each use. Apply product to the affected area using cotton or soft cloth, as often as needed for comfort.

**Children under 2 years of age:** Consult a doctor before use.

**Other Information.**

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

**Inactive Ingredients.**

Bentonite Magma, Calcium Hydroxide, Glycerin, Purified Water.

Distributed by AmerisourceBergen  
1300 Morris Drive, chesterbrook, PA 19087

**Questions or Comments?**

1-800-662-3435 [www.goodneighborpharmacy.com](http://www.goodneighborpharmacy.com)

**Good Neighbor Label**



NDC 24385-407-96

# Calamine Topical Suspension USP

External Analgesic / Skin Protectant

Phenolated



6 FL OZS (177 mL)

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active Ingredients</b>	Calamine 8%.....Skin protectant Zinc Oxide 8%.....Topical Analgesic Liquefied Phenol 1%.....
<b>Uses</b>	Dries the oozing and weeping and temporarily relieves pain and itching of poison ivy, poison oak, and poison sumac, or other minor skin irritations.
<b>Warnings</b>	<ul style="list-style-type: none"> <li>For external use only. Use only as directed.</li> <li>Avoid contact with eyes and mucous membranes.</li> <li>Do not apply to large areas of the body or in large quantities, particularly over raw or blistered areas.</li> <li>If applied to fingers or toes do not bandage.</li> <li>Ask a doctor before using on children under 2 years of age.</li> </ul>
<b>When using this product</b>	Discontinue use if condition worsens or does not improve within 7 days and consult a doctor.
<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 (Shake well before using)</b>	Adults and children 2 years of age and older: Cleanse the skin with soap and water and let dry before each use. Apply product to the affected area using cotton or soft cloth, as often as needed for comfort.
<b>Children under 2 years of age:</b>	Consult a doctor before use.
<b>Other information</b>	Store at room temperature 15-30°C (59-86°F)
<b>Inactive ingredients</b>	Bentonite Magma, Calcium Hydroxide, Glycerin, Purified Water.

Distributed by: AmerisourceBergen  
1300 Morris Drive, Cheslerbrook, PA 19087  
Questions or Comments? 311-800-662-3435 • [www.goodneighborpharmacy.com](http://www.goodneighborpharmacy.com)



0 87701 40067 4  
ABC# 919-528 R10111TRLG

## Sunmark Label

NDC 49348-802-34

# phenolated calamine lotion USP

Skin protectant  
External analgesic

0 10939 14733 2

Distributed by McKesson  
One Post Street, San Francisco, CA 94104  
Money Back Guarantee

6 FL OZ (177 mL)

**Drug Facts**

Active Ingredients	Purpose
Calamine, Zinc Oxide	
Liquid Phenol 1%.....	External Analgesic/Skin Protectant

**Uses** Dries the oozing and weeping, and temporarily relieves itching of poison ivy, poison oak, and poison sumac and other minor skin irritations.

**Warnings** For External Use Only. Use only as directed.  

- Avoid contact with eyes and mucous membranes.
- Do not apply to large areas of the body.
- If applied to fingers or toes do not bandage.
- Ask a doctor before using on children under 2 years of age.

**When using this product**  
Discontinue use if condition worsens, or does not improve within 7 days and consult a doctor.

**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 yrs. of age and older	Shake well before using. Cleanse the skin with soap and water. Let dry before each use. Apply lotion to the affected area using cotton or soft cloth, not more than 3 to 4 times daily.
Children under 2 yrs. of age	Consult a doctor before use.

**Inactive ingredients** Bentonite Magma, Calcium Hydroxide, Glycerin, and Purified Water.

**Other information** Store at room temperature 15° - 30° (59°-86°F).

## CALAMINE PHENOLATED TOPICAL SUSPENSION

calamine and zinc oxide and phenol lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82645-921
<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	160 mg in 1 mL
<b>PHENOL</b> (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	10 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>BENTONITE</b> (UNII: A3N5ZCN45C)	
<b>CALCIUM HYDROXIDE</b> (UNII: PF5DZW74VN)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82645-921-96	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	01/01/2008	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(82645-921) , analysis(82645-921) , pack(82645-921) , label(82645-921)

Revised: 12/2023

Pharma Nobis, LLC