

CALAMINE PHENOLATED TOPICAL SUSPENSION- calamine and zinc oxide and phenol lotion
Humco Holding Group, Inc

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 1%

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.

Principal Display Panel

The image shows the principal display panel for Calamine Lotion Phenolated. It features a white background with purple and black text. On the left, there is a 'Drug Facts' box with a table of active ingredients and their purposes. Below this is a 'First Aid' section with a list of uses. The central part of the panel has the product name 'CALAMINE LOTION PHENOLATED' in large, bold, purple letters, with '(CALAMINE TOPICAL SUSPENSION USP)' in smaller text below it. To the right of the product name is a purple vertical bar with the text 'First Aid' and a list of uses: 'External analgesic', 'Skin protectant', 'Drying agent', and 'Itch relief'. Below the product name is the HUMCO logo and the text 'A trusted name in home health care'. At the bottom right, there is a 'Drug Facts (continued)' box with 'Directions', 'Other information', and 'Inactive ingredients'. A barcode is located on the right side of the panel, with the number '03950 40796 8' printed below it. The text 'RD41420' is printed below the barcode.

| Active Ingredients | Purpose |
|----------------------------|-------------------|
| Calamine 8%, Zinc Oxide 8% | Skin protectant |
| Liquorol Phenol 1% | Topical analgesic |

Uses Dries the oozing and weeping and temporarily relieves pain and itching of poison ivy, poison oak, and poison sunae, insect bites 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.
- 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, does not improve or if symptoms persist for more than 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.

Continued >

First Aid

- External analgesic
- Skin protectant
- Drying agent
- Itch relief

Drug Facts (continued)

Directions

- Adults and children 2 years of age and older: Shake well before using. Cleanse the skin with soap and water and let dry before each use. Apply lotion 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 15-30°C (59-86°F)

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

RD41420

HUMCO, Teawake, TX 75901
Questions or Comments? ☎ 1-800-862-9435
"We Help People Feel Better"

*Go to: www.simplehomeremedies.com
to find helpful hints and learn more about Calamine Lotion Phenolated.

| Drug Facts | |
|---|-------------------|
| Active ingredients | Purpose |
| Calamine 8%, Zinc Oxide 8%..... | Skin protectant |
| Liquefied Phenol 1%..... | Topical Analgesic |
| Uses Dries the oozing and weeping and temporarily relieves pain and itching of poison ivy, poison oak, and poison sumac, insect bites or other minor skin irritations. | |
| Warnings | |
| <ul style="list-style-type: none"> ■ 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, does not improve or if symptoms persist for more than 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. | |
| <i>Continued</i> ▶ | |

CALAMINE LOTION PHENOLATED

(CALAMINE TOPICAL SUSPENSION USP)



First Aid

- External analgesic
- Skin protectant
- Drying agent
- Itch relief

6 fl oz
(177 mL)

| Drug Facts (CONTINUED) | |
|--|--|
| Directions | |
| <ul style="list-style-type: none"> ■ Adults and children 2 years of age and older: Shake well before using. Cleanse the skin with soap and water and let dry before each use. Apply lotion to the affected area using cotton or soft cloth, as often as needed for comfort. ■ Children under 2 years age: Consult a doctor before use. | |
| Other information | |
| Store at room temperature 15-30°C (59-86°F) | |
| Inactive ingredients | |
| Bentonite Magma, Calcium Hydroxide, Glycerin, Purified Water. | |

R011918

HUMCO, Texarkana, TX 75501
Questions or Comments? ☎1-800-662-3435
"We Help People Feel Better"

*Go to: www.simplehomeremedies.com
to find helpful hints and learn more about Calamine Lotion Phenolated.



CALAMINE PHENOLATED TOPICAL SUSPENSION

calamine and zinc oxide and phenol lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0395-0407 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 160 mg in 1 mL |
| PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV) | PHENOL | 10 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BENTONITE (UNII: A3N5ZCN45C) | |
| CALCIUM HYDROXIDE (UNII: PF5DZW74VN) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0395-0407-96 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/13/2017 | |

Marketing Information

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

Labeler - Humco Holding Group, Inc (825672884)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|---|
| Pharma Nobis, LLC | | 118564114 | manufacture(0395-0407) , pack(0395-0407) , analysis(0395-0407) , label(0395-0407) |

Revised: 12/2023

Humco Holding Group, Inc