# CALAMINE- calamine 8% and zinc oxide 8% lotion Humco Holding Group, 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.

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### **Private Label Calamine Lotion**

**Drug Facts** 

## **Active Ingredients**

Calamine 8% and Zinc Oxide 8%

## **Purpose**

Skin protectant

## Uses

dries the oozing and weeping o poison ivy, poison oak, and poison sumac.

## Warnings

For external use only. Use only as directed.

Avoid contact with eyes and mucous membranes.

Ask a doctor before using on chilren 6 months 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 chidren 2 years of age and older: shake well before using. Cleanse the skin with soap and water and let it dry befroe each use. Apply lotion to the affected area using a 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 13-30C (50-86F)

## **Inactive ingredients**

Bentonite magma, calcium hydroxide, glycerin, purified water.

## **Good Neighbor Label**



### **Health Care Label**



## **Quality Choice Label**

Drug Facts

Calamine 8%, Zinc Oxide R%

Warnings

membranes.

6 months of age.

consult a doctor.

immediately.

Active ingredients

ivy, poison oak, and poison sumac.



## Select Brand Label

# Drug Facts Active ingredients Purpose Calamine 8%,

Zinc Oxide 8%.....Skin protectant

Uses Dries the oozing and weeping of poison ivy, poison oak, and poison sumac.

## Warnings

- For External use only. Use only as directed.
- Avoid contact with eyes and mucous membranes.
- Ask a doctor before using on children under 6 months of age.

When using this product Discontinue use if condition worsens, does not improve or if symptoms persist for more than 7 days, or clear up and occur again within a few 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.

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Calamine Topical Suspension USP

Drying Agent . Skin Protectant

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## 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 6 months age: Consult a doctor before use.

#### Other information

Store at room temperature 15-30°C (50-86°F)

## Inactive ingredients

Avicel, Bentonite Magma, Calcium Hydroxide, Carrageenan, Glycerin, Purified Water, and Xanthan Gum.

R050315RLG

Distributed By: select brand\*/distributors Pine Bluff, AR 71603 USA AC 870-535-3635 MADE IN USA



## Sun Mark Label



#### **Premier Value**



## 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 6 months age: Consult a doctor before use.

Other information Store at room temperature 15-30°C (50-86°F)

Inactive ingredients Avicel, Bentonile Magma, Calcium Hydroxide, Carrageenan Glycerin, Purified Water, and Xanthan Gum.

Questions or Comments? © 1-800-662-3435

Distributed By. Chain Drug Consortium, LLC UPARC, Blog, A3, Surie 338 1020 William Pitt Way Pittsburgh, PA 15238 www.chaindrugconsortium.com

MADE IN USA

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund



## Fred's Calamine

# Drug Facts Active ingredients Calamine 8%,

Calamine 8%,
Zinc Oxide 8%
Skin protectant

Uses Dries the oozing and weeping of poison ivy, poison oak, and poison sumac

Purpose

### Warnings

- For External use only. Use only as directed.
- Avoid contact with eyes and mucous membranes.
- Ask a doctor before using on children under 6 months of age.

When using this product Discontinue use if condition worsens, does not improve or if symptoms persist for more than 7 days, or clear up and occur again within a few 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.

MADE IN USA



## 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 6 months age: Consult a doctor before use.

#### Other information

Store at room temperature 15-30°C (50-86°F)

## Inactive ingredients

Avicel, Bentonite Magma, Calcium Hydroxide, Carrageenan, Glycerin, Purified Water, and Xanthan Gum.

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DISTRIBUTED BY: fred's, Inc. 4300 NEW GETWELL RD, MEMPHIS, TN 38118 www.fredsinc.com



### **DDM Label**



## **Rite Aid Label**



### Harris Teeter Label

#### Drug Facts Purpose Active ingredients Calamine 8%, Zinc Oxide 8%. Skin protectant

Uses Dries the oozing and weeping of poison ivy, poison oak, and poison sumac

### Warnings

- For External use only. Use only as directed. Avoid contact with eyes and mucous
- membranes
- Ask a doctor before using on children under 6 months of age.

When using this product Discontinue use if condition worsens, does not improve or if symptoms persist for more than 7 days, or clear up and occur again within a few 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 )



## Skin Protectant • Drying Agent

Topical relief of minor irritations due to: Poison Ivy, Poison Oak and Poison Sumac.

6 FL OZ (177 mL)

## 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 6 months age: Consult a doctor before use.

#### Other information

Store at room temperature 15-30°C (50-86°F)

#### Inactive ingredients

Avicel, Bentonite Magma, Calcium Hydroxide, Carrageenan, Glycerin. Purified Water, and Xanthan Gum.

R050315DL

PROUDLY DISTRIBUTED BY: HARRIS TEETER, LLC MATTHEWS, NC 28105

your*plus*guarantee.

1-800-432-6111 or harristeeter.com

MADE IN USA

## **Health Mart Label**

## Drug Facts

Active ingredients

Purpose

Calamine 8% Zinc Oxide 8%

Skin protectani

Uses Dries the oozing and weeping of poison ivy, poison cak, and poison sumac

#### Warnings

- For External use only. Use only as directed. Avoid contact with eyes and mucous
- 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, or clear up and occur again within a few 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 Continued

NDC 62011-0114-Health Mart.

## Calamine Lotion

Calamine Topical Suspension USP

Drying agent · Skin protectant

6 Fl oz (177 mL)

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 colton 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

Avicel, Bentonite Magma, Calcium Hydroxide, Carrageenan, Glycerin, Purified Water, and Xanthan Gum.

#### **MSKESSON**

Another Quality Product Distributed by McKesson One Post Street, San Francisco, CA 94104 Money Back Guarantse healthmart.com R09221

### **Dollar Tree Label**



NDC 45591-041-96

## CALAMINE LOTION

(Calamine Topical Suspension USP)

## SKIN PROTECTANT



CONTENTS 6 FL OZ (177 mL)

## **Drug Facts**

## Active ingredients

Calamine 8%, Zinc Oxide 8%...

## Purpose

.Skin protectant

Dries the oozing and weeping of poison ivy, poison oak, poison sumac.

## Warnings

For External use only. Use only as directed.

When using this product Do not get in eyes.

#### 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 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 6 months age: Consult a doctor before use.

Other information ■ Store at room temperature 15-30°C

Inactive ingredients Avicel, Bentonite Magma, Calcium Hydroxide, Carrageenan, Glycerin, Purified Water, and Xanthan Gum.

Distributed by: Pierson Laboratories, PO Box 157, Saluda, NC 28773 Questions or Comments? @1-800-662-3435

## **Equate Label**

#### Drug Facts

Active ingredients Calamine 8%

Purpose

Zinc Oxide 8% ...Skin protectant

Uses Dries the oozing and weeping of poison ■ ivy ■ oak ■ sumac

## Warnings

For external use only

When using this product ■ do not get into eyes

Stop use and ask a doctor if

■ condition worsens ■ symptoms last 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 (1-800-222-1222) right away.

Continued >



- Skin protectant
- Poison Ivy, Oak and Sumac drying lotion

6 FL OZ (177mL)

## 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, no more than 3 to 4 times daily.
- 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, Carageenan, Glycerin, Microcrystalline Cellulose, Purified Water, and Xanthan Gum.

#### **DISTRIBUTED BY: Walmart Inc.** Bentonville, AR 72716

Satisfaction guaranteed - For question comments please call 1-888-287-1915.

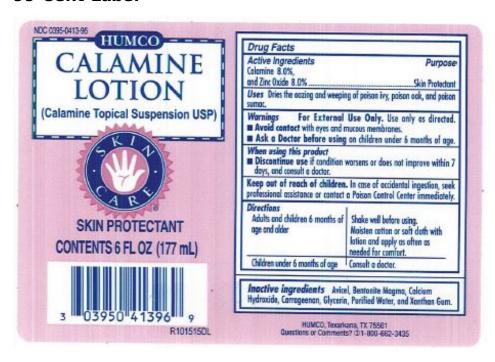








## 99 Cent Label



**Top Care Label** 

## **Drug Facts** Active ingredients

Purpose

JDC 36800-702-96

Calamine 8%.

Zinc Oxide 8% .Skin protectant

Uses Dries the oozing and weeping of poison ivy, poison oak, and poison sumac.

#### Warnings

- For External use only. Use only as directed ■ Avoid contact with eyes and mucous membranes
- Ask a doctor before using on children under 2 years of age

Stop use and ask a doctor if condition worsens, does not improve or if symptoms persist for more than 7 days, or clear up and occur again within a

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center 1-800-222-1222 immediately.

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**✓ QUALITY GUARANTEED** 



# **Calamine Lotion** USP

TOPICAL SUSPENSION USP

**Drying Lotion for:** Poison Ivy, Oak & Sumac

6 FL OZ (177 mL)

#### 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 age: Consult a doctor before use

#### Other information

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

#### Inactive ingredients

Avicel, Bentonite Magma, Calcium Hydroxide, Carageenan, Glycerin, Purified Water, and Xanthan Gum



DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007@ TOPCO HHGA0521 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com



Scan here for more information or call 1-888-423-0139

## Drug Facts

#### Active ingredients Calamine 8%,

Purpose

Zinc Oxide 8%

Uses Dries the oozing and weeping of poison ivy, poison cak, and poison sumac.

- Warnings
   For External use only. Use only as directed
   Avoid contact with eyes and mucous
- Ask a doctor before using on children under 2 years of age

Stop use and ask a doctor if condition worsens, does not improve or if symptoms persist for more than 7 days, or clear up and occur again within a

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center 1-800-222-1222 immediately

Continued N



# Calamine Lotion USP

CALAMINE TOPICAL SUSPENSION USP

Drying Lotion for: Poison Ivy, Oak & Sumac



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 age: Consult a doctor before use

## Other information

Store at room temperature 15-30°C

## Inactive ingredients

Avicel, Bentonite Magma, Calcium Hydroxide, Carageenan, Glycerin, Purified Water, and Xanthan Gum

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6 FL OZ (177 mL)

### **Assured Label**



500 VOLVO PARKWAY, QUESTIONS OR COMMENTS? J1-800-662-3435



#### Drug Facts

#### Active ingredients

Purpose Calamine 8% Skin protectant Skin protectant Zinc Oxide 8%

Uses Dries the oozing and weeping of poison lvy, poison oak,

## Warnings ... For external use only ... Use only as directed

- · Avoid contact with eyes and mucous membran
- 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, or clear up and occur again within a few 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 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.

#### Other information

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

#### Inactive ingredients

Avicel, Bentonite Magma, Calcium Hydroxide, Carageenan, Glycerin, Purified Water, and Xanthan Gum.

6 FL OZ (177 mL)

## **CALAMINE**

calamine 8% and zinc oxide 8% lotion

## **Product Information**

**Product Type HUMAN OTC DRUG** NDC:0395-9110 Item Code (Source)

**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

**Inactive Ingredients Ingredient Name** Strength CARRAGEENAN (UNII: 5C69YCD2YJ) XANTHAN GUM (UNII: TTV12P4NEE) CALCIUM HYDROXIDE (UNII: PF5DZW74VN) **GLYCERIN** (UNII: PDC6A3C0OX) WATER (UNII: 059QF0KO0R) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) **BENTONITE** (UNII: A3N5ZCN45C)

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:0395- 9110-96	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 final	part347	03/25/1998						

## Labeler - Humco Holding Group, Inc. (825672884)

## **Registrant -** Humco Holding Group, Inc. (825672884)

Establishment							
Name	Address	ID/FEI	Business Operations				
Humco Holding Group, Inc.		825672884	label(0395-9110), manufacture(0395-9110), analysis(0395-9110), pack(0395-9110)				

Revised: 12/2021 Humco Holding Group, Inc.