

HEALTH CARE CALAMINE- calamine 8% and zinc oxide 8% lotion
Great Lakes Wholesale, Marketing and Sales 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.

Health Care Calamine Lotion

Drug Facts

active Ingredients

Calamine 8%

Zinc Oxide 8%

Purpose

Skin Protectant

Skin Protectant

Uses

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

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 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 6 mo. 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, as often as needed for comfort.

Children under 6 mo. of age: Consult a doctor before use.

Other information

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

Inactive Ingredients

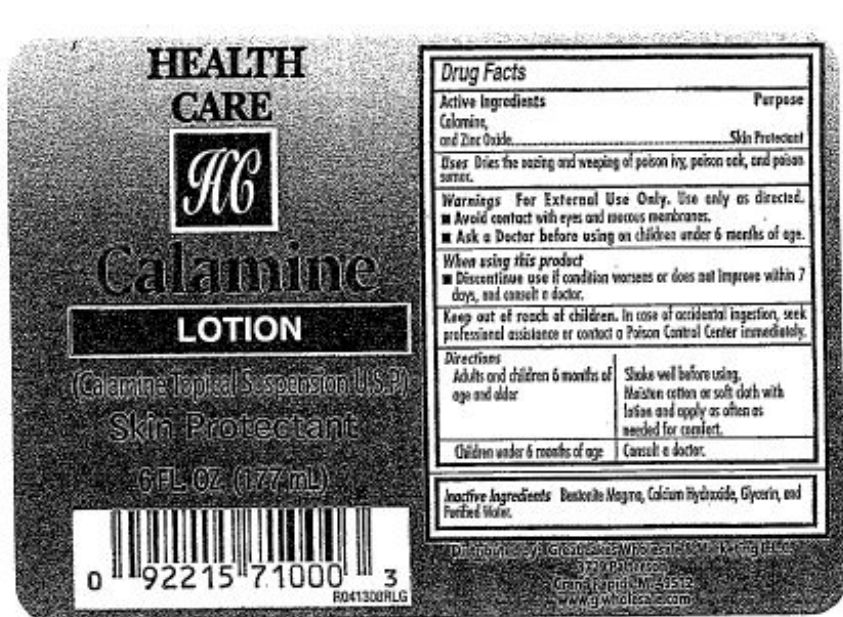
Bentonite Magma, Calcium Hydroxide, Glycerin, and Purified Water.

Questions or Comments?

Label

<p>Drug Facts</p> <table border="1"> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> <tr> <td>Calamine 8%, Zinc Oxide 8%.....</td> <td>Skin protectant</td> </tr> </table> <p>Uses Dries the oozing and weeping of poison ivy, poison oak, and poison sumac</p> <p>Warnings</p> <ul style="list-style-type: none"> ■ 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. <p>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.</p> <p>Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.</p> <p style="text-align: right;"><i>Continued</i> ▶</p>	Active ingredients	Purpose	Calamine 8%, Zinc Oxide 8%.....	Skin protectant	 <p>HEALTH CARE™</p> <p>CALAMINE LOTION</p> <p>(Calamine Topical Suspension USP)</p> <p>Skin Protectant</p>	<p>Drug Facts (CONTINUED)</p> <p>Directions</p> <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 6 months age: Consult a doctor before use. <p>Other information Store at room temperature 15-30°C (50-86°F)</p> <p>Inactive ingredients Avicel, Bentonite Magma, Calcium Hydroxide, Carrageenan, Glycerin, Purified Water, and Xanthan Gum.</p>
Active ingredients	Purpose					
Calamine 8%, Zinc Oxide 8%.....	Skin protectant					
<p>6 FL.OZ. (177 mL)</p>		<p>MADE IN USA</p>				

New Label



The new label features a dark background with the 'HEALTH CARE' logo at the top, followed by the 'HC' logo. The product name 'Calamine LOTION' is prominently displayed, with '(Calamine Topical Suspension USP)' and 'Skin Protectant' below it. The volume '6 FL. OZ. (177 mL)' is also shown. A barcode is located at the bottom left. The 'Drug Facts' panel is on the right side, containing the following information:

Drug Facts

Active Ingredients	Purpose
Calamine and Zinc Oxide.....	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 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 6 months of age and older	Shake well before using. Moisten cotton or soft cloth with lotion and apply as often as needed for comfort.
Children under 6 months of age	Consult a doctor.

Inactive Ingredients Bentonite Magma, Calcium Hydroxide, Glycerin, and Purified Water.

Distributed by: Great Lakes Wholesale & Marketing L.L.C.
3729 Patterson, Grand Rapids, MI 49512
www.glwholesale.com

HEALTH CARE CALAMINE

calamine 8% and zinc oxide 8% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64092-413
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
BENTONITE (UNII: A3N5ZCN45C)	
CALCIUM HYDRIDE (UNII: WY779SQ0XW)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-413-96	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/27/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2008	

Labeler - Great Lakes Wholesale, Marketing and Sales Inc (361925498)

Registrant - Humco Holding Group, Inc. (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc.		825672884	manufacture(64092-413) , analysis(64092-413) , pack(64092-413) , label(64092-413)

Revised: 12/2018

Great Lakes Wholesale, Marketing and Sales Inc