

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

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.

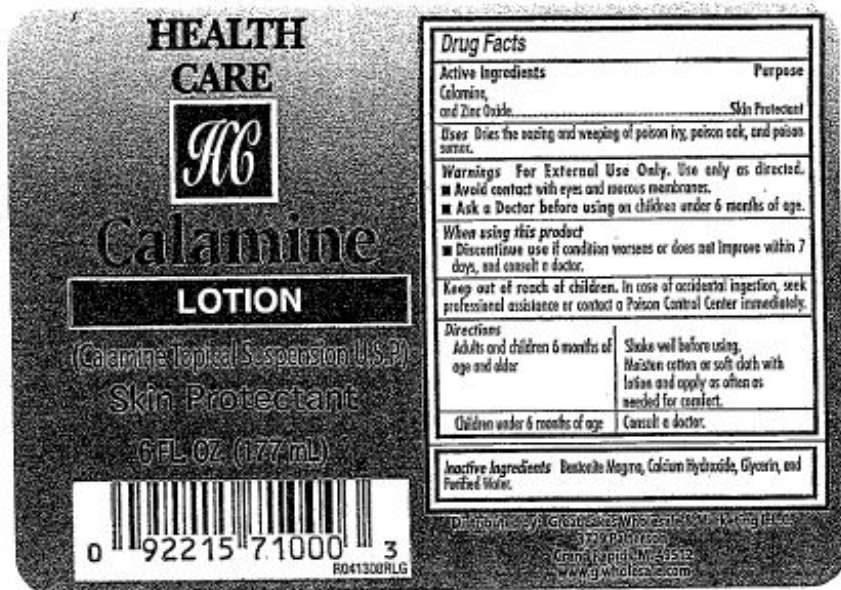
Questions or Comments?

Label

Drug Facts Active ingredients Calamine 8%, Zinc Oxide 8%.....Skin protectant Purpose 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 ▶	 HEALTH CARE™ CALAMINE LOTION (Calamine Topical Suspension USP) Skin Protectant	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: Great Lakes Wholesale & Marketing L.L.C. 3729 Patterson , Grand Rapids, MI 49512 www.glwholesale.com	 0 92215 71000 3
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6 FL.OZ. (177 mL) MADE IN USA

New Label



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 Drug	M016	01/01/2008	

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

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(64092-413) , analysis(64092-413) , pack(64092-413) , label(64092-413)

Revised: 12/2023

Great Lakes Wholesale, Marketing and Sales Inc