

PREMIERE VALUE CALAMINE- calamine 8% and zinc oxide 8% lotion
Chain Drug Consortium

Premiere Value 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	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.	
<i>Continued</i> ▶	

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

Distributed By: R050115DL
Chain Drug Consortium, LLC
UPARC, Bldg. A3, Suite 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

PREMIERE VALUE CALAMINE

calamine 8% and zinc oxide 8% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-413
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:68016-413-96	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 - Chain Drug Consortium (101668460)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(68016-413) , analysis(68016-413) , pack(68016-413) , label(68016-413)

Revised: 12/2023

Chain Drug Consortium