

ASSURED CALAMINE- calamine 8% and zinc oxide 8% lotion
Greenbriar International

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.

Assured Calamine

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 children 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 2 years of age and older: shake well before using. Cleanse the skin with soap and water and let it dry before each use. Apply lotion to the affected area using a cotton or soft cloth, as often as needed for comfort.

Children under 6 months 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.

assured calamine

ASSURED
SKIN PROTECTANT
Calamine Lotion
Topical Suspension, USP

- Poison Ivy, Oak, Sumac Drying Lotion

DISTRIBUTED BY
GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY,
CHESAPEAKE, VA 23320
QUESTIONS OR COMMENTS?
1-800-662-3435

RT02419
3927785140
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Drug Facts

Active ingredients	Purpose
Calamine 8%.....	Skin protectant
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

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)

ASSURED CALAMINE

calamine 8% and zinc oxide 8% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-4130
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	160 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-4130-6	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/27/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part347	01/27/2020	

Labeler - Greenbriar International (610322518)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	label(33992-4130) , manufacture(33992-4130) , analysis(33992-4130) , pack(33992-4130)

Revised: 3/2022

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