

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

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

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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
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	160 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	

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 Drug	M016	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: 12/2023

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