

CALAMINE- calamine and zinc oxide lotion
Pharma Nobis, LLC

Freskaro Calamine Lotion

Drug Facts

Active Ingredients

Calamine 8% and Zinc Oxide 8%

Uses

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

Purpose

Skin protectant

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.

Stop use and ask a doctor if

condition worsens, does not improve or if symptoms last 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 (1-800-222-1222) right away.

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, not more than 3 to 4 times daily as needed for comfort.

Children under 2 years of age: Consult a doctor before use

Other information

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

Inactive ingredients

Avicel, Bentonite Magma, Calcium Hydroxide, Glycerin, Purified Water, and Xanthan Gum

Questions

Questions or Comments? 1-833-551-0932


label

Freskaro
refresh & revitalize

Calamine Lotion
Topical Solution, USP

- Skin Protectant
- Poison ivy, poison oak, & poison sumac

6 fl. oz (177mL)

Drug Facts	Purpose
Active ingredient 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 2 years of age.
Stop use and ask a doctor if	condition worsens, does not improve or if symptoms last 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 (1-800-222-1222) right away.
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, not more than 3 to 4 times daily as needed for comfort. • Children under 2 years of age: Consult a doctor before use.
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.
Questions or Comments?	1-833-551-0932
Manufactured by: Pharma Nobis, LLC 7400 Alumax Dr, Texarkana, TX 75501 R122022	
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CALAMINE

calamine and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82645-418
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	80 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82645-418-96	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/16/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	05/16/2023	

Labeler - Pharma Nobis, LLC (118564114)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	label(82645-418) , manufacture(82645-418) , analysis(82645-418) , pack(82645-418)

Revised: 12/2023

Pharma Nobis, LLC