

SUNMARK CALAMINE- calamine 8% and zinc oxide 8% lotion
Strategic Sourcing Services LLC

Sunmark 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.

Package Principal Display Panel

sunmark® NDC 49348-011-34

calamine lotion
(Calamine Topical Suspension USP)

Skin protectant
6 FL OZ (177 mL)

Drug Facts	
Active ingredients	Purpose
Calamine 8%.....	Skin protectant
Zinc Oxide 8%.....	Skin protectant
Uses Dries the oozing and weeping of poison: ■ ivy ■ oak ■ sumac.	
Warnings For external use only. When using this product ■ do not get into eyes. Stop use and ask a doctor if ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	

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 2 years of age: Consult a doctor before use.	
Other information Store at room temperature 15°C to 30°C (59°F to 86°F)	
Inactive ingredients Avicel, Bentonite Magma, Calcium Hydroxide, Carageenan, Glycerin, Purified Water, and Xanthan Gum.	

R032622
Distributed by McKesson Corp., via Strategic Sourcing Services LLC, Memphis, TN 38141
You may report side effects to 833-358-6431 Monday to Friday 9:00am to 7:00pm EST
Money Back Guarantee
Please visit us at www.sunmarkbrand.com
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Calamine 8%.....	Skin protectant
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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.	

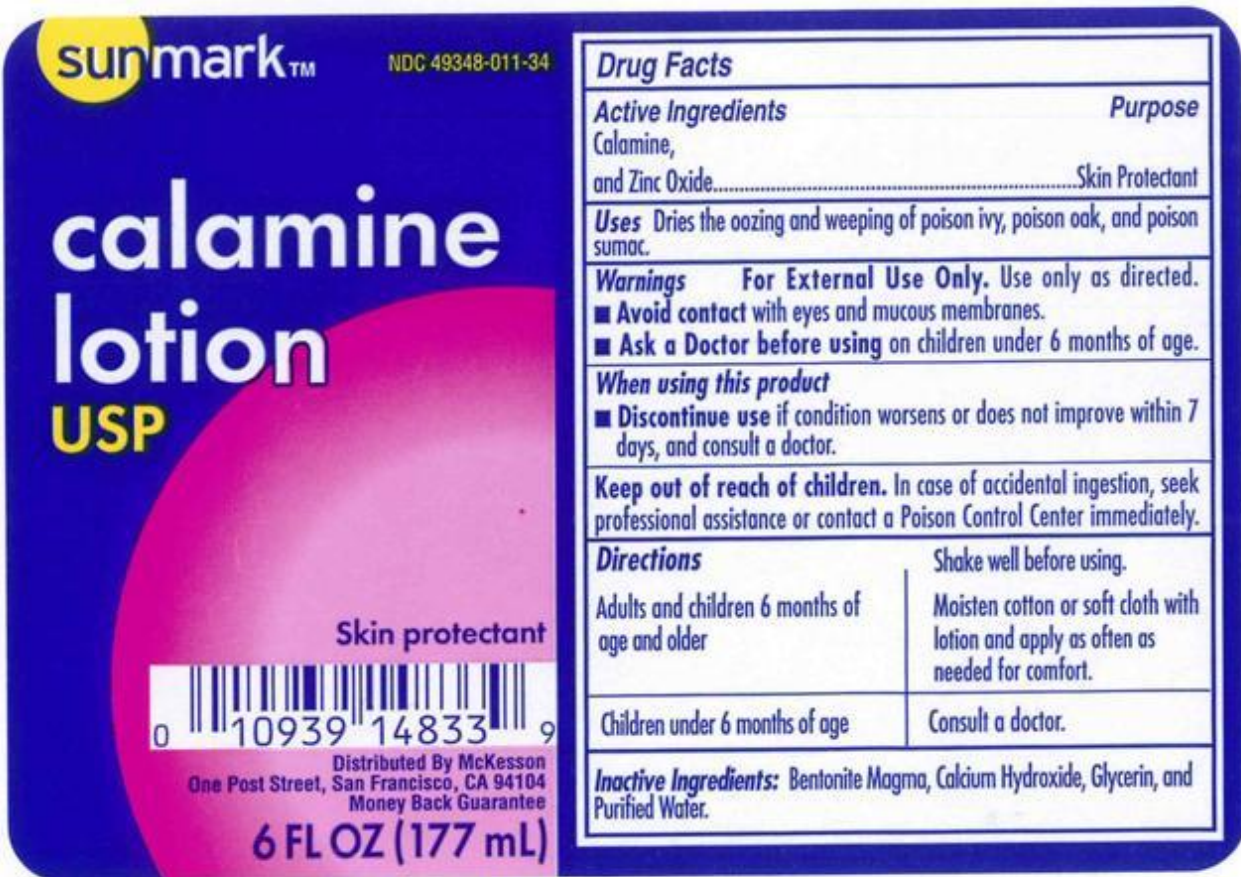
Drug Facts (CONTINUED)	
Directions ■ Adults and children 2 years of age and older: Shake well before using. Cleanse the skin with soap and water and let dry before each use. Apply lotion to the affected area using cotton or soft cloth, as often as needed for comfort. ■ Children under 6 months of age: Consult a doctor before use.	
Other information Store at room temperature 15-30°C (50-85°F)	
Inactive ingredients Avicel, Bentonite Magma, Calcium Hydroxide, Carrageenan, Glycerin, Purified Water, and Xanthan Gum.	

R05315RLG
McKesson
Distributed by McKesson
One Post Street
San Francisco, CA 94104
Money Back Guarantee

MADE IN USA

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Label



SUNMARK CALAMINE

calamine 8% and zinc oxide 8% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-011
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
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
GLYCERIN (UNII: PDC6A3COOX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-011-34	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/12/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	01/01/2008	

Labeler - Strategic Sourcing Services LLC (116956644)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	label(49348-011) , manufacture(49348-011) , pack(49348-011) , analysis(49348-011)

Revised: 12/2023

Strategic Sourcing Services LLC