

CALAMINE- calamine, zinc oxide lotion
Consumer Product Partners, LLC

Swan 063.001/063AA
Calamine Lotion

Active ingredients

Calamine 8%

Zinc oxide 8%

Purpose

Skin protectant

Use

dries the oozing and weeping of poison: • i vy • 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.

Directions

- shake well before using
- apply as needed

Other information

store at 59° - 86°F

Inactive ingredients

bentonite magma, calcium hydroxide, glycerin, purified water

Adverse reaction

Distributed by:

Consumer Product Partners, LLC,

St. Louis, MO 63114

1-888-593-0593

Principal Panel Display

SWAN®

Calamine Lotion

- Calamine topical Suspension USP
- Skin Protectant
- Poison Ivy, Oak, Sumac Drying Lotion

6 FL OZ (177 mL)

The image displays the front and back panels of a Calamine Lotion container. The front panel features the Swan logo and the product name 'Calamine Lotion' in large white text on a red background. Below the name, it lists three uses: Calamine Topical Suspension USP, Skin Protectant, and Poison Ivy, Oak, Sumac Drying Lotion. The volume '6 FL OZ (177 mL)' is printed at the bottom. The back panel is divided into several sections: 'Drug Facts' (Active ingredients: Calamine 8%, Zinc oxide 8%; Purpose: Skin protectant), 'Use' (dries oozing and weeping of poison ivy, oak, and sumac), 'Warnings' (external use only, avoid eyes, stop if symptoms worsen), 'Directions' (shake well, apply as needed), 'Other information' (store at 59°-86° F), and 'Inactive ingredients' (bentonite magma, calcium hydroxide, glycerin, purified water). The Spanish side of the label includes 'Información sobre medicamentos', 'Ingredientes activos', 'Propósito', 'Uso', 'Advertencias', 'Instrucciones', and 'Otra información'. A barcode with the number 0 79068 00435 0 is located at the bottom center. A small yellow box with the number '3' is in the top right corner of the back panel. The distributor information 'Distributed by: Consumer Product Partners, LLC, St. Louis, MO 63114, 1-888-593-0593' and the code 'L0002037SD' are at the bottom right.

CALAMINE

calamine, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11344-063
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 OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-063-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1998	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	07/15/1989	

Labeler - Consumer Product Partners, LLC (119091520)**Registrant** - Consumer Product Partners, LLC (119091520)**Establishment**

Name	Address	ID/FEI	Business Operations
Consumer Product Partners, LLC		119091514	manufacture(11344-063)

Revised: 3/2025

Consumer Product Partners, LLC