

CALAMINE - ferric oxide red lotion
Perrigo Direct, Inc.

Calamine Lotion
063.001/063AA

Active ingredients

Calamine 8%
Zinc oxide 8%

Purpose

Skin protectant

Use

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

Directions

- shake well before using
- apply as needed

Other information

store at 59° - 86°F

Inactive ingredients

bentonite magma, calcium hydroxide, glycerin, purified water

Distributed by: Perrigo Direct, Inc.

Peachtree City, GA 30269

www.PerrigoDirect.com

1-888-593-0593

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Principal Panel Display

GOODSENSE

NDC 75981-063-30

Calamine Lotion

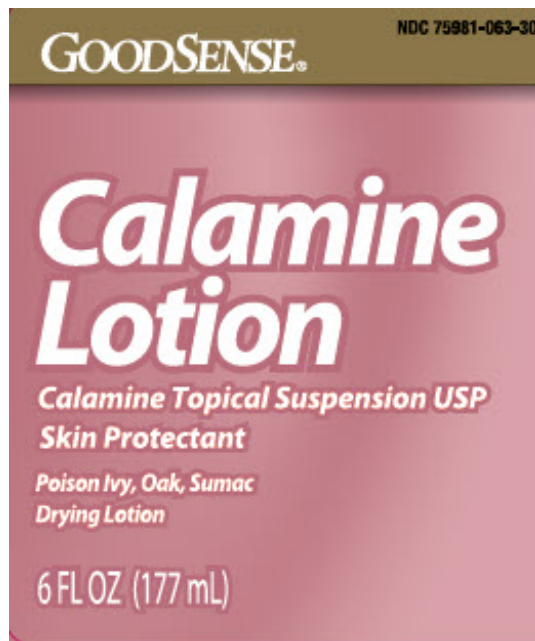
Calamine Topical Suspension USP

Skin Protectant

Poison Ivy, Oak, Sumac

Drying Lotion

6 FL OZ (177 mL)



CALAMINE

ferric oxide red lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:75981-063

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	8 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8 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:75981-063-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1992	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	09/15/1992	

Labeler - Perrigo Direct, Inc. (076059836)

Registrant - Vi-Jon, LLC (088520668)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(75981-063)

Establishment

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Vi-Jon, LLC		088520668	manufacture(75981-063)

Revised: 10/2023

Perrigo Direct, Inc.