

CALAMINE- ferric oxide red lotion
Better Living Brands, LLC

Signature Care 063.001/063AA
Calamine Lotion

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

Adverse Reaction

DISTRIBUTED BY BETTER LIVING BRANDS LLC

P.O. BOX 99, PLEASANTON, CA 94566-0009

1-888-723-3929 www.betterlivingbrandsLLC.com

QUALITY & SATISFACTION GUARANTEED OR YOUR MONEY BACK

principal display panel

NDC 21130-941-30

Signature Care™

Quality Guaranteed

Calamine Lotion

Calamine Topical Suspension U.S.P.

Skin Protectant

Poison Ivy, Oak, Sumac Drying Lotion

6 FL OZ (177 mL)

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Calamine Topical Suspension U.S.P.

Skin Protectant Poison Ivy, Oak, Sumac Drying Lotion

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CALAMINE

ferric oxide red lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-941
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:21130-941-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	06/15/2015	

Labeler - Better Living Brands, LLC (009137209)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(21130-941)