# CALAMINE - ferric oxide red lotion Better Living Brands LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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# Signature Care 063.001 063AA

# **Active ingredents**

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

# Inactive ingredients

bentonite magma, calcium hydroxide, glycerin, purified water

#### **Adverse Reaction**

DISTRIBUTED BY BETTER LIVING BRANDS LLC
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# principal display panel

Signature Care Quality Guaranteed

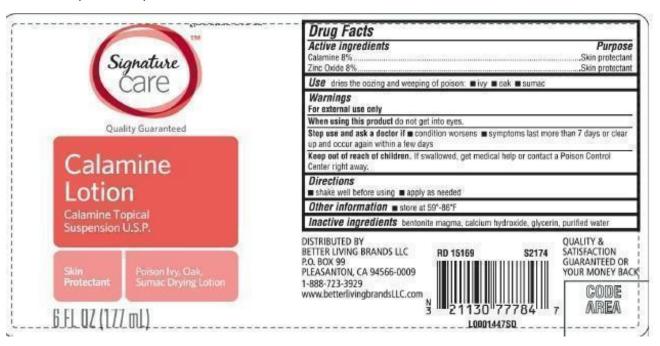
Calamine Lotion

Calamine Topical Suspension U.S.P.

Skin Protectant

Poion Ivy, Oak, Sumac Drying Lotion

6 FL OZ (177 mL)



# ferric oxide red lotion Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-941

# **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	8 g 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: PF5DZ W74VN)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
			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 final	part347	06/15/2015	

# **Labeler -** Better Living Brands LLC (009137209)

# Registrant - Vi Jon, LLC (790752542)

# EstablishmentNameAddressID/FEIBusiness OperationsVi Jon, LLC088520668manufacture(21130-941)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(21130-941)

Revised: 4/2022 Better Living Brands LLC