

**CALAMINE - ferric oxide red lotion**  
**DZB 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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**Calamine Lotion**

**Active ingredient**

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: DZA Brands, LLC

Salisbury, NC 28147/Scarborough, ME 04074

For product questions or concerns

contact us at 1-866-322-2439

Made in the USA with US and foreign components

**principal display panel**

NDC 55316-063-26

healthy

accents

calamine lotion

calamine topical suspension USP

skin protectant

- poison ivy
- oak
- sumac drying lotion

Net 6 FL OZ (177mL)

NDC 55316-063-30

healthy accents<sup>®</sup>

# calamine lotion

calamine topical suspension USP

skin protectant  
poison ivy, oak and  
sumac drying lotion



NET 6 FL OZ (177 mL)

## CALAMINE

ferric oxide red lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55316-063
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	80 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	80 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENTONITE</b> (UNII: A3N5ZCN45C)	
<b>CALCIUM HYDROXIDE</b> (UNII: PF5DZW74VN)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>water</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-063-26	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2008	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/05/2008	

**Labeler** - DZB Brands, LLC (090322194)

**Registrant** - Vi-Jon, LLC (790752542)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55316-063)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55316-063)

Revised: 12/2022

DZB Brands, LLC