

**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

063.001/063AA

**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

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:55316-063 |
| 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: 059QF0K00R)             |          |

## 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 (790752542)

## Establishment

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

Revised: 8/2019

DZB Brands, LLC