

CALAMINE- ferric oxide red lotion
Old East Main Co.

Rexall 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

Visit us at: Rexall.com

or call 1-866-4REXALL

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

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principal display panel

Since 1903

REXALL®

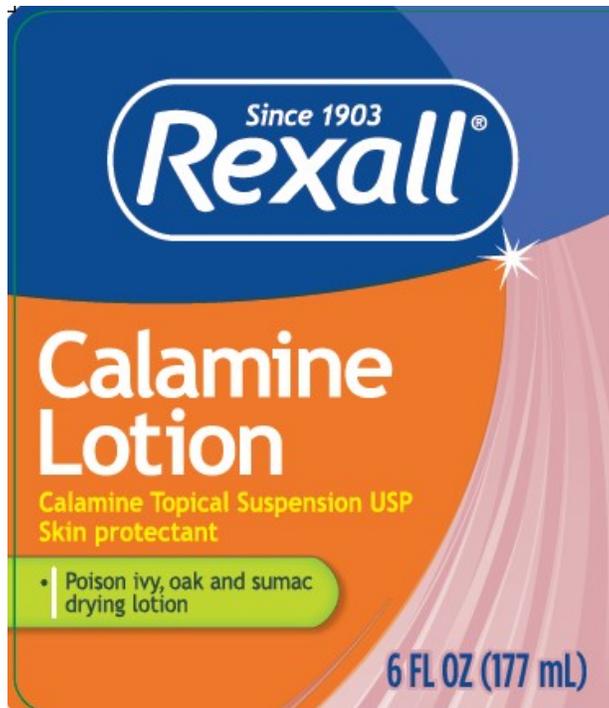
Calamine Lotion

Calamine Topical Suspension USP

Skin Protectant

• Poison ivy, oak and sumac drying lotion

6 FL OZ (177 mL)



| | |
|--|-----------------|
| Drug Facts | |
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CALAMINE

ferric oxide red lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55910-063 |
| 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: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:55910-063-30 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/13/2009 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M016 | 04/13/2009 | |

Labeler - Old East Main Co. (068331990)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|------------------------|
| Nice-Pak Products, LLC | | 119091514 | manufacture(55910-063) |