

**CALAMINE- ferric oxide red lotion**  
**Major Pharmaceuticals**

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**Major 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

**Questions or comments?**

(800) 616-2471

**Adverse reactions**

Distributed By:

MAJOR PHARMACEUTICALS

17177 N LAUREL PARK DRIVE, SUITE 233

Livonia, MI 48152

Re-Order No 014282 M-97

Rev. 10/16

**principal display panel**

NDC 0904-2533-21

MAJOR<sup>®</sup>

Calamine

Lotion

Calamine Topical Suspension USP

Skin Protectant

Poison Ivy, Oak, Sumac

Drying Lotion

Shake well before using

6 FL OZ (177 mL)

NDC 0904-2533-21



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Skin Protectant  
Poison Ivy, Oak, Sumac  
Drying Lotion**



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### Drug Facts

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L0013301SB

## CALAMINE

ferric oxide red lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-2533
<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)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-2533-21	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/07/2013	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	01/07/2013	

**Labeler** - Major Pharmaceuticals (191427277)

**Registrant** - Consumer Product Partners, LLC (119091520)

## Establishment

Name	Address	ID/FEI	Business Operations
Consumer Product Partners, LLC		119091514	manufacture(0904-2533)

Revised: 4/2025

Major Pharmaceuticals