

**CALAMINE- ferric oxide red lotion**  
**Preferred Pharmaceuticals Inc.**

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**Major 063.001 063AA**

**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

**Relabeled By: Preferred Pharmaceuticals Inc.**

**principal display panel**

NDC 68788-0292-1

MAJOR

Calamine

Lotion

Calamine Topical Suspension USP

Skin Protectant

Poison Ivy, Oak, Sumac

Drying Lotion

Shake well before using

6 FL OZ (177 mL)

# Calamine Lotion

Brand Name

Active ingredients: Calamine 8% ... Skin protectant / Zinc oxide 8% ... Skin protectant

**Pkg Size:** Exp Date: ####/####/####  
Lot#: \_\_\_\_\_  
Batch#: \_\_\_\_\_  
Ins: \_\_\_\_\_  
Mfg: Major Pharm.; Livonia, MI  
Prod#: \_\_\_\_\_  
Warning

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 this and all medication out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Store at 59° - 86°F.



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed.

Calamine Lotion  
Qty: Ins:  
Lot: Bat:  
Prod# (NDC):



Directions English

Apply externally \_\_\_\_\_ times a day.  
Use as directed on package.



GTIN  
#####  
SN #####  
EXP #####

**Instrucciones Espanol:**  
 Aplique externamente \_\_\_\_\_ veces al dia.  
 Utilice como dirigido en el paquete.

Calamine Lotion  
Qty: Ins:  
Lot: Bat:  
Prod# (NDC):

Calamine Lotion  
Qty: Ins:  
Insurance NDC:  
Lot: Bat:

Calamine Lotion  
Qty: Ins:  
Lot: Bat:  
Prod# (NDC):

Log  
Chart  
Billing  
Patient

## CALAMINE

ferric oxide red lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68788-0292(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	8 g in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8 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:68788-0292-1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/19/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	347	04/19/2018	

**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals Inc. (791119022)

**Establishment**

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-0292)

Revised: 2/2025

Preferred Pharmaceuticals Inc.