

CALAMINE- ferric oxide red lotion
Preferred Pharmaceuticals Inc.

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

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):

Calamine Lotion

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

Calamine Lotion

Qty: Ins:
Insurance NDC:
Lot#: Bat#:

Calamine Lotion

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



Directions English

Apply externally _____ times a day.
Use as directed on package.



Instrucciones Espanol:

Aplique externamente _____ veces al día.
Utilice como dirigido en el paquete.

Log

Chart

Billing

Patient

CALAMINE

ferric oxide red lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-0292(NDC:0904-2533)
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	8 g in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8 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: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: 3/2024

Preferred Pharmaceuticals Inc.