CALAMINE- ferric oxide red lotion Major Pharmaceuticals

Major 063.001/063AA Calamine Lotion

Active ingredents

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?

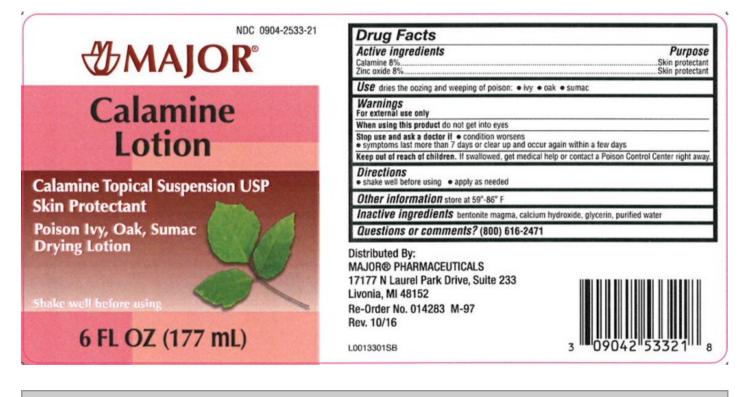
(800) 616-2471

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[®] Calamine Lotion Calamine Topical Suspension USP Skin Protectant Poison Ivy, Oak, Sumac Drying Lotion Shake well before using 6 FL OZ (177 mL)



CALAMINE

ferric oxide red lotion

Product Info	ormation					
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:0904-2533	
Route of Admi	nistration	TOPICAL				
Active Ingree	dient/Active	Moiety				
Ingredient Name					f Strength	
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)				FERRIC OXIDE R	ED 80 mg in 1 m	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)				ZINC OXIDE	80 mg in 1 m	
Inactive Ingr		Strength				
BENTONITE (UNI						
CALCIUM HYDRO						
WATER (UNII: 059						
Packaging						
# Item Code	Pa	ackage Description	Ма	rketing Start Date	Marketing End Date	
1 NDC:0904- 2533-21	177 mL in 1 BO Combination Pro	TTLE, PLASTIC; Type 0: Not oduct	a 01/0	7/2013		

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