CALAMINE- ferric oxide red lotion
Major Pharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Major 063.001 063AA

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 59⁰ - 86⁰ 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 Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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: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 FINAL	part347	01/07/2013	

Labeler - Major Pharmaceuticals (191427277)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(0904-2533)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(0904-2533)

Revised: 4/2022 Major Pharmaceuticals