CALAMINE- ferric oxide red lotion
NuCare Pharmaceuticals,Inc.

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.

Drug Facts

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 59º - 86º 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

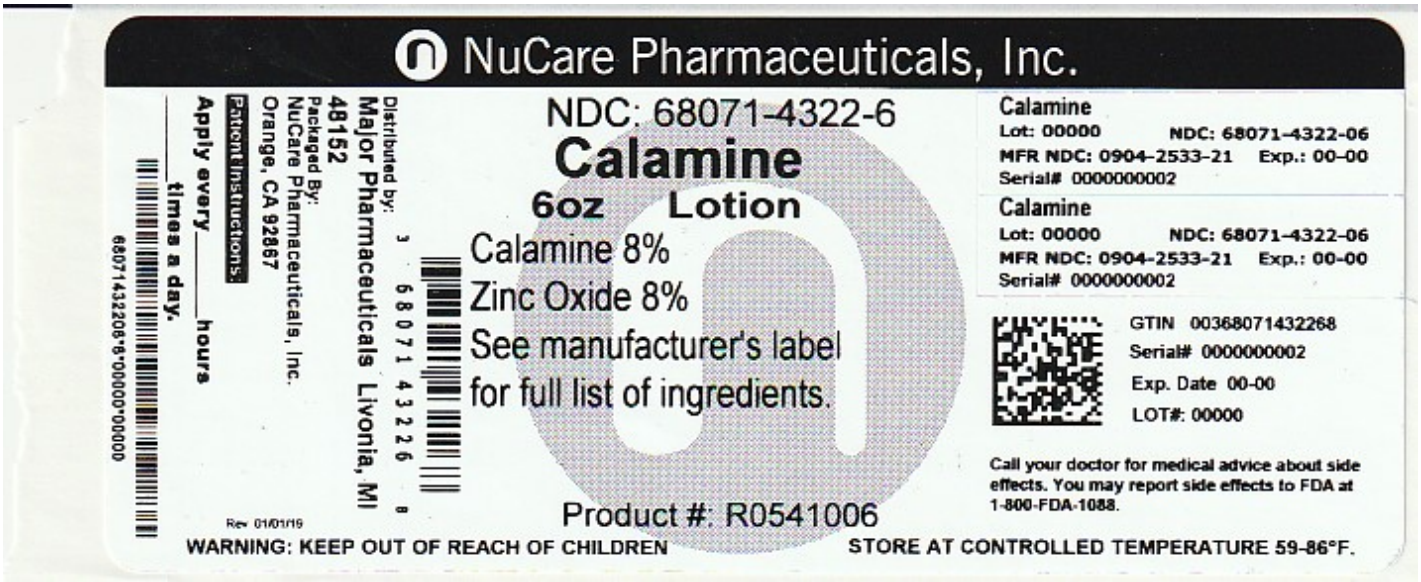
Livonia, MI 48152

Re-Order No 014282 M-97

Rev. 10/16

063.000/063AA

Principal Display Panel



CALAMINE

ferric oxide red lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-4322(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:68071-4322-6	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/08/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/07/2013	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-4322)

Revised: 7/2023 NuCare Pharmaceuticals,Inc.