

CALAMINE- ferric oxide red lotion
Major Pharmaceuticals

Major 063.001/063AA
Calamine Lotion

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?

1-888-593-0593

Adverse reactions

Distributed By:

MAJOR ® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

www.major-rugby.com

Rev. 03/25 M-97 Re-order No. 014283

principal display panel

NDC 0904-2533-21

MAJOR ®

Calamine Lotion

Calamine Topical Suspension USP

Calamine 8%, Zinc Oxide 8%

Skin Protectant

dries the oozing and weeping of poison: ivy, oak, and sumac

Shake well before using

6 FL OZ (177 mL)

MAJOR[®]

NDC 0904-43-21

calamine lotion

calamine topical suspension USP
calamine 8%, zinc oxide 8%
skin protectant

dries the oozing and weeping
of poison: ivy, oak, and sumac

shake well before using

6 FL OZ (177 mL)

Drug Facts

Active Ingredients	Purpose
Calamine 8%	Skin protectant
Zinc oxide 8%	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? 1-888-383-0583

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MAJOR[®] PHARMACEUTICALS
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Rev. 03/25 M-57 Re-order No. 014283



L0013301SC

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	80 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	80 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 Drug	M016	01/07/2013	

Labeler - Major Pharmaceuticals (191427277)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(0904-2533)

Revised: 2/2026

Major Pharmaceuticals