

CALAMINE- ferric oxide red lotion
Topco Associates LLC

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.

top Care 063

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

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063.001/063AA

principal display panel

NDC 36800-063-30

TOPCARE Calamine Lotion

CALAMINE TOPICAL SUSPENSION USP

SKIN PROTECTANT

POISON IVY, OAK SUMAC DRYING LOTION

6 FL OZ (177 mL)



CALAMINE

ferric oxide red lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-063
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:36800-063-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1991	
2	NDC:36800-063-26	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1991	05/28/2021
3	NDC:36800-063-34	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1991	05/28/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/15/1991	

Labeler - Topco Associates LLC (006935977)

Registrant - Vi Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(36800-063)

Revised: 5/2021

Topco Associates LLC