

CALAMINE - ferric oxide red lotion

Wakefern Food Corp

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 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

Adverse Reaction Section

DISTRIBUTED BY
WAKEFERN FOOD CORP.
5000 RIVERSIDE DRIVE
KEASBEY, NJ 08832
063.001/063AA

principal display panel

ShopRite

SKIN PROTECTANT

CALAMINE

LOTION

CALAMINE TOPICAL SUSPENSION U.S.P.

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:41190-063
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:41190-063-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1989	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/15/1989	

Labeler - Wakefern Food Corp (069722418)**Registrant** - Vi Jon (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(41190-063)