

CALAMINE- calamine, pramoxind hcl 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.

Medicated Calamine Lotion
336.002/336AF

Active ingredients

Calamine 8%

Pramoxind HCl 1%

Purpose

Skin protectant

External analgesic

Use

- for the temporary relief of pain and itching associated with minor skin irritations and rashes due to poison ivy, poison oak, or poison sumac
- 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

- condition worsens
- symptoms last more than 7 days or clean 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 applying was affected are of skin

Adults and children 2 years of age and older - apply to affected area not more than 3 to 4 times daily

Children under 2 years of age - do not use, ask a doctor

Other information

store at room temperature (59°-77°F)

Inactive ingredients

alcohol, camphor, diazolidinyl urea, fragrance, hypromellose, methylparaben, oil of lavender, oil of rosemary, polysorbate 80, propylene glycol, propylparaben, purified water, xanthan gum

Disclaimer

This product is not manufactured or distributed by Valeant Pharmaceuticals, distributor of Caladryl Lotion

Adverse reactions

DIST. BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL

@TOPCO VIJA071

QUESTIONS? 1-888-423-0139

topcare@topco.coM

www.topcarebrand.com

336.002/336AF

principal display panel

TopCare

Health

COMPARE TO

CALADRYL LOTION

ACTIVE INGREDIENTS

MEDICATED

Calamine

Lotion

EXTERANAL ANALGESIC/

SKIN PROTECTANT

Drying Action Plus

Itch Relief for:

Poison Ive, Oak & Sumac

OUR PHARMACISTS RECOMMEND

6 FL OZ (177 mL)



CALAMINE

calamine, pramoxind hcl lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-336
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
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	

DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-336-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/21/2009	

Labeler - Topco associates LLC (006935977)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(36800-336)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(36800-336)

Revised: 1/2023

Topco associates LLC