

CALAMINE- calamine, pramoxine hcl lotion
Meijer Distribution

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
336.003/AG

Active ingredients

Calamine 8%

Pramoxine HCl 1%

Purpose

Skin protectant

External analgesic

Uses

- 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, benzyl alcohol, camphor, fragrance, hydroxypropyl methylcellulose, Lavandula angustifolia (lavender) oil, phenoxyethanol, polysorbate 80, propylene glycol, Rosmarinus officinalis (rosemary) leaf oil, water, xanthan gum

Our Quality Guarantee

WWW.MEIJER.COM/SATISFACTION

*This product is not manufactured or distributed by Bausch Health US, LLC, distributor of Caladryl Lotion Calamine Plus Itch Reliever

DISTRIBUTED BY MEIJER DISTRIBUTION, INC.

GRAND RAPIDS, MI 49544

www.meijer.com

Principal Panel Display

NDC 79481-0336-1

Compare to Caladryl Lotion*

MEDICATED

calamine

lotion

External Analgesic/Skin Protectant

Drying Action Plus Itch Relief

Relieves itching due to insect

bites, poison oak or ivy, or

other minor skin irritation

6 FL OZ (177 mL)

Empty & Replace Cap

Plastic Bottle

how2recycle.info



CALAMINE

calamine, pramoxine hcl lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79481-0336
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)	
benzyl alcohol (UNII: LKG8494WBH)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
phenoxyethanol (UNII: HIE492ZZ3T)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
propylene glycol (UNII: 6DC9Q167V3)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
water (UNII: 059QF0KO0R)	
xanthan gum (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79481-0336-1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/17/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/17/2009	

Labeler - Meijer Distribution (006959555)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(79481-0336)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(79481-0336)