

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.

Meijer Medicated Calamine
336.002/AF

Active ingredients

Calamine 8%

Pramoxine 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

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

DIST. BY MEIJER

DISRIBUTION, INC

GRAND RAPIDS, MN 49544

www.meijer.com

principal display panel

NDC 41250-888-30

Compare to Caladryl Lotion

Meijer

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)

NDC 41250-888-30

meijer

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Caladryl®
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MEDICATED calamine lotion

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6 FL OZ (177 mL)

CALAMINE

calamine, pramoxine hcl lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-888
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 (SYNTHETIC) (UNII: 5TJD82A1ET)
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:41250-888-30	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(41250-888)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(41250-888)