

CALAMINE- calamine, pramoxine hcl lotion CDMA

**Quality Choice 336.003/336AG
Medicated Calamine Lotion**

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 area 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

Disclaimer

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

ADVERSE REACTION

Distributed by CDMA, Inc.

Novi, MI 48375

www.qualitychoice.com

Questions: 800-935-2362

SATISFACTION GUARANTEED

100% QC

PRINCIPAL DISPLAY PANEL

NDC 83324-053-06

QC

QUALITY CHOICE

*Compare to CALADRYL

Medicated

Calamine


Lotion

External Analgesic/Skin Protectant

For relief from pain and itching due to:

Poison Ivy, Poison Sumac, Insect Bites, Poison Oak & Minor Skin Irritations

6 FL OZ (177 mL)



3 **QC QUALITY CHOICE**

NDC 83324-053-06

*Compare to CALADRYL®

Medicated Calamine Lotion

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External Analgesic / Skin Protectant

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Insect Bites, Poison Oak
& Minor Skin Irritations

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Drug Facts

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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 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 applying wash affected area 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, phenoxethanol, polysorbate 80, propylene glycol, Rosmarinus officinalis (rosemary) leaf oil, water, xanthan gum

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CALAMINE

calamine, pramoxine hcl lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-053
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 (NATURAL) (UNII: N20HL7Q941)	
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:83324-053-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/26/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	02/26/2025	

Labeler - CDMA (011920774)

Registrant - Consumer Product Partners, LLC (119091520)

Establishment			
Name	Address	ID/FEI	Business Operations
Consumer Product Partners, LLC		119091514	manufacture(83324-053)

Revised: 2/2025

CDMA