

CALAMINE- calamine, pramoxine 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
336.003 336AG

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

DISTRIBUTED BY TOPCO ASSOCIATES LLC,

ELK GROVE VILLAGE, IL 60007

TOPCO VIJa0622 QUESTIONS? 1-888-423-0139

topcare@topco.com www.topcarebrand.com

Quality Guaranteed

Visit here for more information: <http://topbrnds.com/4901jm>

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

principal display panel

TopCare Health

COMPARE TO CALADRYL LOTION ACTIVE INGREDIENTS*

NDC 76162-336-30

MEDICATED

Calamine Lotion

EXTERANAL ANALGESIC/SKIN PROTECTANT

For Relief from Pain & Itching Due to:

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

6 FL OZ (177 mL)

NDC 76162-336-30



COMPARE TO
CALADRYL® LOTION
ACTIVE INGREDIENTS*

Medicated Calamine Lotion

EXTERNAL ANALGESIC / SKIN PROTECTANT

For Relief from Pain & Itching Due to:

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

6 FL OZ (177 mL)

CALAMINE			
calamine, pramoxine hcl lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-336
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	80 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:76162-336-30	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(76162-336)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(76162-336)

Revised: 8/2022

Topco associates LLC