

CALAMINE- calamine, pramoxine hcl lotion
Topco Associates LLC

Top Care 336.003/336AG
Medicated Calamine Lotion

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 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

ADVERSE REACTION

DISTRIBUTED BY TOPCO ASSOCIATES LLC,

ELK GROVE VILLAGE, IL 60007

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topcare@topco.com www.topcarebrand.com

Quality Guaranteed

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

Disclaimer

*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*

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For Relief from Pain & Itching Due to:

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Drug Facts

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Calamine 8%	Skin protectant
Pramoxine HCl 1%	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, phenoxyethanol, polysorbate 80, propylene glycol, Rosmarinus officinalis (rosemary) leaf oil, water, xanthan gum

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QUALITY GUARANTEED

L0020580SA



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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	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ALCOHOL (UNII: 3K9958V90M)	
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 Drug	M016	05/21/2009	

Labeler - Topco Associates LLC (006935977)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(76162-336)

Revised: 2/2026

Topco Associates LLC