

CALAMINE- calamine, pramoxind hcl lotion
Walgreen CO

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.

Drug Facts

Active ingredients

Calamine 8%

Pramoxind 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 if

- 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 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, camphor, diazolidinyl urea, fragrance, hypromellose, methylparaben, oil of lavender, oil of rosemary, polysorbate 80, propylene glycol, propylparaben, purified water, xanthan gum

Rear label text

Distributed by: WALGREEN CO.

200 WILMOT RD., DERRFIELD, IL 60015

100% SATISFACTION GUARANTEED

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L001621SC

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

Walgreens pharmacist recommended

Walgreens Pharmacist survey study. November 2016.

336.002/336AF

principal display panel

Walgreens

Calahist

Medicated Calamine Lotion/External Analgesic/Skin Protectant

Drying action plus itch relief

Compare to Caladryl Lotion active ingredients ††

6 FL OZ (177 mL)

Walgreens

Compare to Caladryl® Lotion
active ingredients†

Calahist

MEDICATED CALAMINE
LOTION / EXTERNAL
ANALGESIC /
SKIN PROTECTANT

- Drying action plus
itch relief

6 FL OZ (177 mL)

CALAMINE

calamine, pramoxine hcl lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9114
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	8.6 mg in 1 mL
zinc oxide (UNII: SOI2LOH54Z) (zinc oxide - UNII:SOI2LOH54Z)	zinc oxide	20 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)	
CAMPBOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9114-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/07/2017	

Labeler - Walgreen CO (008965063)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(0363-9114)