#### CALAMINE- calamine, pramoxine hcl lotion Amazon.Com Services 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.

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### Medicated Calamine Anti-Itch Lotion 336.003/336AG

#### **Active ingredients**

Calamine 8%

Pramoxine HCl 1%

#### Purpose

Skin protectant

External analgesic

#### Uses

- for the temporary relief of pain and itching associated with minot 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

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"Alexa, reorder Amazon Basics Anti-Itch Lotion." alexa

#### Principal display panel

amazon basics medicated calamine lotion External Analgesic Skin Protectant Anti-itch lotion

6 FL OZ (177 mL)

amazon basics

# medicated calamine lotion

External Analgesic Skin Protectant Anti-itch Lotion

## 6 FL OZ (177 mL)

#### CALAMINE

calamine, pramoxine hcl lotion

Product Information						
Product Type	HUMAN OTC DRUG Item Code (Source)		NDC:72	NDC:72288-436		
Route of Administration	TOPICAL	TOPICAL				
Active Ingredient/Active Moiety						
Ingredient Name Basis of Streng				ngth	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			S	Strength		
ALCOHOL (UNII: 3K9958V90M)						
BENZYL ALCOHOL (UNII: LKG8494	WBH)					

CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

#### Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288- 436-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2018	

#### **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/21/2018	
o re monograph mar	parts in	00,21,2010	

#### Labeler - Amazon.Com Services LLC (128990418)

#### Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Vi-Jon, LLC		790752542	manufacture(72288-436)	

#### Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Vi-Jon, LLC		088520668	manufacture(72288-436)

Revised: 9/2023

Amazon.Com Services LLC