

CALAMINE- zinc oxide, ferric oxide red, pramoxine hcl lotion
Navarro Discount Pharmacies, 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.

Drug Facts

Active ingredients

Calamine 8%

Pramoxine HCl 1%

Purpose

Skin protectant

Topical analgesic

Uses

temporarily relieves pain and itching associated with:

- rashes due to poison ivy, poison oak or poison sumac
- insect bites
- minor skin irritation
- minor cuts

dries the oozing and weeping of poison ivy, poison oak and poison sumac

Warnings

For external use only.

When using this product

do not get into eyes

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days
- symptoms persist for 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 use
- 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: ask a doctor

Other information

- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

SD alcohol 38-B, camphor, diazolidinyl urea, fragrance, hypromellose, methylparaben, polysorbate 80, propylene glycol, propylparaben, purified water, xanthan gum

Package Label

NDC #59970-075-01

Vida Mia
mi salud

*Compare to the active ingredients of Caladryl®.
*Compare con los ingredientes activos de Caladryl®.

Calamine Lotion

Loción de Calamina

■ Protects Skin ■ Relieves Itching ■ Topical Analgesic
■ Protege la piel ■ Alivia la piquiña ■ Analgésico tópico

NET 6 oz (177 mL)

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 minor cuts
■ dries the oozing and weeping of poison ivy, poison oak and poison sumac

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*This product is not manufactured or distributed by Johnson & Johnson Consumer Companies, Inc., owner of the registered trademark Caladryl®.

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CALAMINE

zinc oxide, ferric oxide red, pramozine hcl lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59970-075
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	80 mg in 1 mL
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)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59970-075-01	177 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/03/2013	

Labeler - Navarro Discount Pharmacies, LLC (094930963)

Registrant - Kareway Product, Inc. (121840057)

