CALDYPHEN CLEAR- pramoxine hydrochloride and zinc acetate lotion Amerisource Bergen

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.

Caldyphen Clear

Drug Facts

Active Ingredient

Pramoxine HCl 1%

Purpose

External analgesic

Active Ingredient

Zinc Acetate 0.1%

Purpose

Skin protectant

Uses

Dries the oozing and weeping, and temporarily relieves pain and itching of poison ivy, poison oak, and poison sumac and other minor skin irritations.

Warnings

For External Use Only. Use only as directed. Avoid contact with eye and mucous membranes. ask a doctor before using on children under 2 years of age.

Stop use and as a doctor if

condition worsens. Symptoms last for more than 7 days or celar up and occur again whitin a few days.

Keep out of reach of children

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

Adults and children 2 yrs. of age and older. Shake well before using. cleanse the skin with soap and water. Let dry before each use. apply lotion to the affected area using cotton or soft cloth, not more than 3 to 4 times daily as needed for comfort.

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Inactive Ingredients

SD alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methylcellulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben, and Purified Water.

Other information

Store at room temperature 15 - 30 (59-86F)

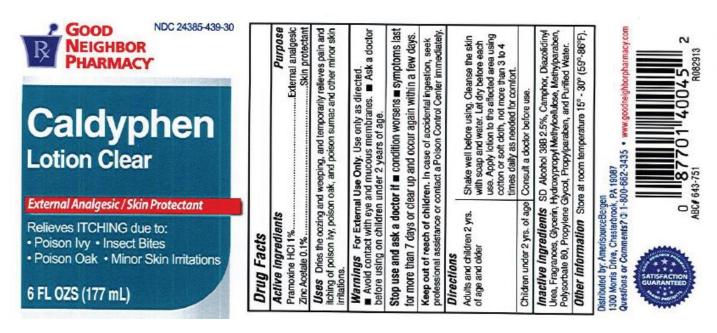
Distributed by: AmerisourceBergen

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Questions or comments?

1-800-662-3435 www.goodneighborpharmacy.com

Principal Display Panel



CALDYPHEN CLEAR

pramoxine hydrochloride and zinc acetate lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24385-439
Route of Administration	TOPICAL		

ctive Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PRAMO XINE HYDRO CHLO RIDE (UNII: 88 AYB8 67L5) (PRAMO XINE - UNII: 068 X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

l	Packaging	ackaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:24385-439- 30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2013		

Marketing Info	Iarketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	0 1/0 1/20 0 8		

Labeler - Amerisource Bergen (007914906)

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