

SUNMARK CALDIPHEN- calamine and pramoxine hydrochloride lotion
Strategic Sourcing Services

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.

Sunmark Caldiphen Lotion

Drug Facts

Active Ingredients

Calamine 8%

Pramoxine HCl 1%

Purpose

Skin Protectant

External analgesic

Uses

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

Warnings

For external use only. Use only as directed.

When using this product. Avoid contact with eyes and mucous membranes.

Stop use and ask a doctor if

condition worsens. Symptoms last for more than 7 days or clear up and occur again within 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 yr. of age and older. Shake well before using. Cleanse the skin with soap and water and let dry. Apply to the affected area using cotton or soft cloth, not more than 3 to 4 times daily as needed for comfort.

Children under 2 yrs. of age. Consult a doctor before use.

Inactive Ingredients

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

Other information

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

Principal Display Panel

Label

sunmark™ COMPARE TO CALADRYL® LOTION™ ACTIVE INGREDIENT* NDC 49348-337-36

caldyphen lotion

Skin protectant
External analgesic

0 10939 14533 8

Distributed By McKesson
One Post Street, San Francisco, CA 94104
Money Back Guarantee

6 FL OZ (177 mL)

Drug Facts	
Active Ingredients	Purpose
Pramoxine HCl 1% and Calamine 8%.....	External Analgesic/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.	
When using this product Discontinue use if condition worsens, does not improve or if symptoms persist for more than 7 days or clear up and occur again within a few days, and consult a doctor.	
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.
Children under 2 yrs. of age	Consult a doctor before use.
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°-86°F).	

*Caladryl® Lotion™ is the registered trade mark of Warner-Lambert Co.

SUNMARK CALDIPHEN

calamine and pramoxine hydrochloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-337
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	80 mg in 1 mL
PRAMO XINE HYDRO CHLORIDE (UNII: 88 AYB867L5) (PRAMO XINE - UNII:068 X84E056)	PRAMO XINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-337-36	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/02/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/25/1998	

Labeler - Strategic Sourcing Services (116956644)

Registrant - Humco Holding Group, Inc. (825672884)