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 Caldyphen 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 moucous membranes.

Stop ue and ask a doctor if

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

Keep out of reach of children.

In case of accidental ingestion, seek profesional 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 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
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE 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)

Revised: 12/2019 Strategic Sourcing Services