SUNMARK CALDYPHEN CLEAR- zinc acetate and pramoxine hydrochloride lotion
Strategic Sourcing Services LLC

Sunmark Caldyphen Clear Lotion

Drug Facts

Active Ingredients

Zinc Acetate 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.

Ask a doctor before using on children 2 years of age.

Stop use and ask a doctor if

condition worsens. Symptoms last for more than 7 days 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

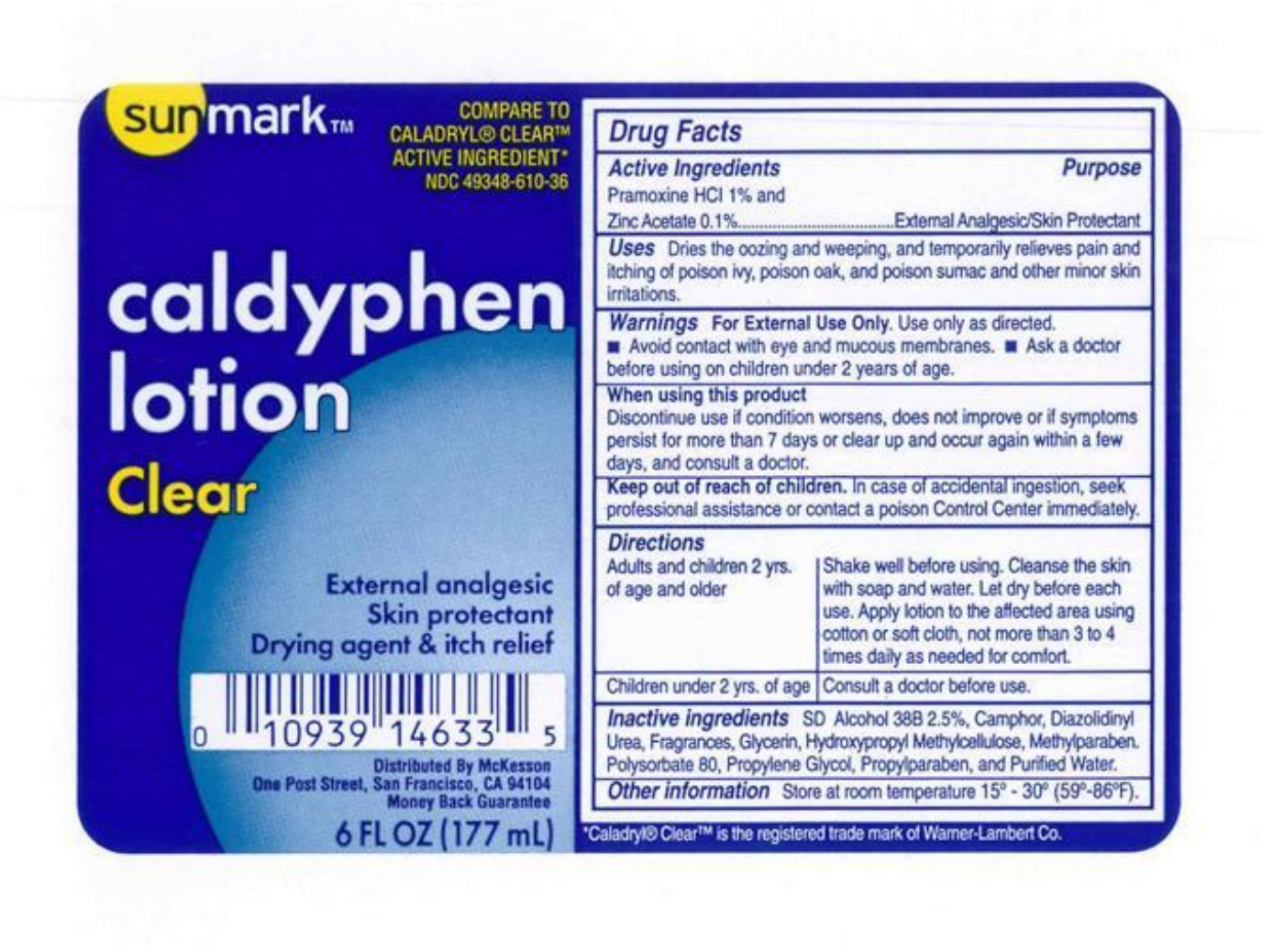
SD Alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methycelulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben and Purified Water.

Other information

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

Principal display panel

Label



SUNMARK CALDYPHEN CLEAR
zinc acetate and pramoxine hydrochloride lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49348-610
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
ALCOHOL (UNII: 3K9958V90M)	
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:49348-610-36	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/12/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	03/25/1998	

Labeler - Strategic Sourcing Services LLC (116956644)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	analysis(49348-610) , manufacture(49348-610) , pack(49348-610) , label(49348-610)