LEADER CALDYPHEN CLEAR- pramoxine hydrochloride, zinc acetate lotion
Cardinal Health

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.

LEADER Caldyphen Clear Lotion

Drug Facts

Active Ingredients

Pramoxine HCl 1%

Zinc Acetate 0.1%

Purpose

- External Analgesic
- Skin Protectant

Uses:

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

Warnings: For external use only. Use only as directed.

- Avoid contact with mucous membranes.

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: (SHAKE WELL BEFORE USING)

- **Adults and children 2 yrs. of age and older:**Apply lotion to the affected area not more than 2 to 4 times daily.
- **Children under 2 yrs. of age:** Consult a doctor.

Other Information:

Store at temperature 15 degrees - 25 degrees C (59 degrees - 77 degrees F)

Inactive Ingredients:

SD Alcohol 38B 2.5% , Camphor, Diazoldinyl Urea, Fragrances, Glycerin, Hydrozyproyl Methylcellulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben and Purified Water.

Distributed by: Cardinal Health Dublin, Ohio 43017 1-800-200-6313 www.myleader.com

All Leader Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

LEADER Caldyphen Clear Lotion 6oz/177ml (37205-281-30)

LEADER CALDYPHEN CLEAR

pramoxine hydrochloride, zinc acetate lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-281
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 mg in 100 mL
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE 2208 (4000 MPA.S) (UNII: 39J80LT57T)	
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:37205-281-30	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/15/2012	

Labeler - Cardinal Health (097537435)

Registrant - Humco Holding Group, Inc. (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc.		825672884	manufacture(37205-281)

Revised: 1/2020 Cardinal Health