HUMCO CALACLEAR- pramoxine hydrochloride and zinc acetate lotion Humco Holding Group, Inc.

Humco Calaclear

Humco Calamine Lotion

Drug Facts

Active Ingredient

Pramoxine HCI 1%

Purpose

External Analgesic

Active Ingredient

Zinc Acetate 0.1%

Purpose

Skin Protectant

Use

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

Warnings

For external use only. Use only as directed.

Avoid contact with eyes 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 and 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 years of age: Consult a doctor before use.

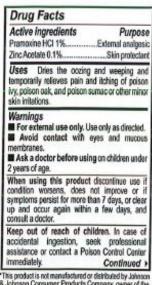
Other Information

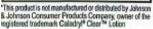
store at room temperature 15 ° - 30 °C (50 ° - 85 °F)

Inactive Ingredient

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

Label









Drug Facts

Active ingredients Purpose

Pramoxine HCl 1% and Zinc Acetate 0.1%

> .External analgesic/ Skin protectant

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

Warnings

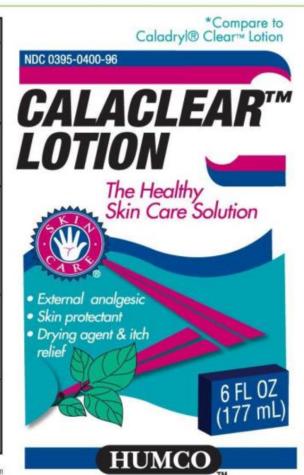
- For external use only. Use only as directed.
- Avoid contact with eyes and mucous membranes.
- Ask a doctor before using on children under 2 years of age.

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. Continued >

This product is not manufactured or distributed by Pfizer, owner of the registered trademark *Caladry(⊛ Clear™ Lotion



Drug Facts (CONTINUED)

Directions

- Adults and children 2 years of age and older: Shake well before using. Cleanse the skin with soap and water and 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 years of age:
- Consult a doctor before use.

Other information

Store at room 15-30°C (50-86°F) temperature

Inactive ingredients

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

R121211.RLG



HUMCO, Texarkana, TX 75501 Questions or Comments? @1-800-662-3435

Go to: www.simplehomeremedies.com to find helpful hints and learn more about Calaclear[™] Lotion.

HUMCO CALACLEAR

pramoxine hydrochloride and zinc acetate lotion

Product Information

NDC:0395-0400 **Product Type** HUMAN OTC DRUG Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
CAMPHOR (NATURAL) (UNII: N20HL7Q941)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
GLYCERIN (UNII: PDC6A3C0OX)		

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHYLPARABEN (UNII: A218C7H19T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
WATER (UNII: 059QF0KO0R)	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
			177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/25/1998	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	03/25/1998	
OTC Monograph Drug	MOT6	03/25/1998	

Labeler - Humco Holding Group, Inc. (825672884)

Registrant - Pharma Nobis, LLC (118564114)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(0395-0400) , analysis(0395-0400) , pack(0395-0400) , label(0395-0400)

Revised: 12/2023 Humco Holding Group, Inc.