QUALITY CHOICE ANTI-ITCH MEDICATED- calamine and pramoxine hydrochloride lotion
CHAIN DRUG MARKETING ASSOCIATION INC

Quality Choice Ati-Itch Medicated 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)

Label

QUALITY CHOICE ANTI-ITCH MEDICATED

calamine and pramoxine hydrochloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-420
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:63868-420-96	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/13/2017	

Marketing Information

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

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(63868-420) , analysis(63868-420) , pack(63868-420) , label(63868-420)

Revised: 8/2023 CHAIN DRUG MARKETING ASSOCIATION INC