

**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 mucous membranes.

Stop use and ask a doctor if

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

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 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

<p>Drug Facts</p> <table border="1"><thead><tr><th>Active Ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Calamine 5%</td><td>Skin protectant</td></tr><tr><td>Painoxone HCl 1%</td><td>External analgesic</td></tr></tbody></table> <p>Indication: Soothes the cooling and weeping and temporarily relieves pain and itching of poison ivy, poison oak, and poison sumac or other minor skin irritations.</p> <p>Warnings</p> <ul style="list-style-type: none">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. <p>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.</p> <p>Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. <i>Continued</i></p>	Active Ingredients	Purpose	Calamine 5%	Skin protectant	Painoxone HCl 1%	External analgesic	<div data-bbox="581 688 699 821"></div> <p data-bbox="841 730 1024 804">*Compare to ingredient in Caladryl® Lotion**</p> <h1 data-bbox="570 835 1003 1073">Anti-Itch Medicated Lotion</h1> <p data-bbox="565 1087 781 1121">Skin protectant</p> <p data-bbox="565 1136 971 1255">External Analgesic Helps Relieve Pain & Itch Caused by Poison Ivy, Poison Oak & Poison Sumac</p> <div data-bbox="878 1199 1013 1331"></div> <p data-bbox="565 1304 753 1346">6 fl oz (177 mL)</p>	<p>Drug Facts (CONTINUED)</p> <p>Directions</p> <ul style="list-style-type: none">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. <p>Other information Store at room temperature 15-30°C (59-86°F)</p> <p>inactive ingredients SD Alcohol 38B 2.5%, Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methycelulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben, Purified Water.</p>	<p>0051415111111</p> <p>35515 95216 4</p>
Active Ingredients	Purpose								
Calamine 5%	Skin protectant								
Painoxone HCl 1%	External analgesic								

*This product is not manufactured or distributed by Johnson & Johnson Consumer Products Company, owner of the registered trademark, Caladryl® Lotion.

Distributed by C.C.M.A., Inc.®
43157 W. Nine Mile
Newell, NE 68376-0695
www.qualitychoice.com
Questions: 248-449-9300
MADE IN USA

Drug Facts

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*Compare to ingredient in Caladryl® Lotion™

Anti-Itch Medicated Lotion

Skin protectant

External Analgesic
Helps Relieve Pain & Itch Caused by Poison Ivy, Poison Oak & Poison Sumac



6 fl OZ (177mL)

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.

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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