

FOSTER AND THRIVE CALDYPHEN CLEAR- pramoxine hydrochloride and zinc acetate lotion
Strategic Sourcing Services, LLC

Foster & Thrive Caldyphen Lotion Clear

Drug Facts

Active Ingredient

Pramoxine HCl 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 (59 ° - 86 °F)

Inactive Ingredient

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

Questions?

Call **833-358-6431**

Label

Drug Facts	Drug Facts (continued)
<p>Active Ingredients</p> <p>Pramoxine HCl 1%..... External Analgesic Zinc Acetate 0.1%..... Skin Protectant</p> <p>Purpose</p>	<p>Directions</p> <p>Adults and children 2 years of age and older: Shake well before using. Cleanse the skin with soap and water. 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.</p> <p>Children under 2 years of age: Consult a doctor before use.</p>
<p>Uses Dries the oozing and weeping, and temporarily relieves pain and itching of • poison ivy • poison oak • poison sumac and other minor skin irritations.</p>	<p>Other Information Store at room temperature 15°-30°C (59°-86°F)</p>
<p>Warnings</p> <p>For external use only. Use only as directed. Avoid contact with eye and mucous membranes.</p> <p>Ask a doctor before use on children under 2 years of age.</p> <p>When using this product do not 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>Inactive ingredients SD Alcohol 38B 2.5% Camphor, Diazolidinyl Urea, Fragrances, Glycerin, Hydroxypropyl Methylcellulose, Methylparaben, Polysorbate 80, Propylene Glycol, Propylparaben, and Purified Water</p>
<p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately. (1-800-222-1222)</p>	<p>Questions? Call 833-358-6431</p> <p>© 2023 McKesson Corporation Distributed by: McKesson Corp. via SSSL, Memphis, TN 38141 Money Back Guarantee www.fosterandthrive.com</p>

FOSTER AND THRIVE CALDYPHEN CLEAR

pramoxine hydrochloride and zinc acetate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1199
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1199-1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/18/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	12/18/2024	

Labeler - Strategic Sourcing Services, LLC (116956644)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	analysis(70677-1199) , pack(70677-1199) , label(70677-1199) , manufacture(70677-1199)