

CALDYPHEN CLEAR- pramoxine hydrochloride and zinc acetate lotion
Amerisource Bergen

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.

Caldyphen Clear

Drug Facts

Active Ingredient

Pramoxine HCl 1%

Purpose

External analgesic

Active Ingredient

Zinc Acetate 0.1%

Purpose

Skin protectant

Uses

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

Warnings

For External Use Only. Use only as directed. Avoid contact with eye and mucous membranes. ask a doctor before using on children under 2 years of age.

Stop use and as 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 yrs. 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.

children under 2 yrs. of age. Consult a doctor before use.

Inactive Ingredients

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

Other information

Store at room temperature 15 - 30 (59-86F)

Distributed by: AmerisourceBergen

1300 Morris Drive, Chesterbrook, PA 19087

Questions or comments ?

1-800-662-3435 www.goodneighborpharmacy.com

Principal Display Panel



| | |
|--|---|
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CALDYPHEN CLEAR

pramoxine hydrochloride and zinc acetate lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:24385-439 |
| 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) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| 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:24385-439-30 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/28/2013 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 01/01/2008 | |

Labeler - Amerisource Bergen (007914906)

Revised: 6/2020

Amerisource Bergen