HUMCO CALAMINE- calamine 8% and zinc oxide 8% lotion Humco holding Group, Inc.

Humco Calamine Lotion

Drug Facts

Active Ingredients

Calamine 8% and Zinc Oxide 8%

Purpose

Skin protectant

Uses

dries the oozing and weeping o poison ivy, poison oak, and poison sumac.

Warnings

For external use only. Use only as directed.

Avoid contact with eyes and mucous membranes.

Ask a doctor before using on chilren 6 months of age.

When using this product

Discontinue use if condition worsens or does not improve within 7 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 chidren 2 years of age and older: shake well before using. Cleanse the skin with soap and water and let it dry befroe each use. Apply lotion to the affected area using a cotton or soft cloth, as often as needed for comfort.

Children under 6 months of age: Consult a doctor before use.

Other information

Store at room temperature 13-30C (50-86F)

Inactive ingredients

Bentonite magma, calcium hydroxide, glycerin, purified water.

Package Principal Display Panel



Drug Facts Active ingredients **Purpose** Calamine 8%, Zinc Oxide 8%. Skin protectant Uses Dries the oozing and weeping of poison ivy, poison oak, and poison sumac. 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 >



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, as often 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 ingredients Avicel, Bentonite Magma, Calcium Hydroxide, Carrageenan, Glycein, Purified Water, and Xanthan Gum.

HUMCO, Texarkana, TX 75501 Questions or Comments? ②1-800-662-3435 "We Help People Feel Better"

*Go to: www.simplehomeremedies.com to find helpful hints and learn more about Calamine Lotion.

MADE IN USA

HUMCO CALAMINE

calamine 8% and zinc oxide 8% lotion

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0395-0413 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | |
|---------------------------------|---|--------------------------|----------------|--|
| | Ingredient Name | Basis of Strength | Strength | |
| | ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 160 mg in 1 mL | |

| Inactive Ingredients | | | | |
|---|----------|--|--|--|
| Ingredient Name | Strength | | | |
| BENTONITE (UNII: A3N5ZCN45C) | | | | |
| CARRAGEENAN (UNII: 5C69YCD2YJ) | | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | | |
| CALCIUM HYDROXIDE (UNII: PF5DZW74VN) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | | |

| Packaging | | | | | |
|-----------|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:0395- 0413-96 | 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 - Humco holding Group, Inc. (825672884)

Registrant - Pharma Nobis, LLC (118564114)

| Establishment | | | | |
|----------------------|---------|-----------|--|--|
| Name | Address | ID/FEI | Business Operations | |
| Pharma Nobis, LLC | | 118564114 | label(0395-0413), manufacture(0395-0413), analysis(0395-0413), pack(0395-0413) | |

Revised: 12/2023 Humco holding Group, Inc.