CALAMINE PLUS PRAMOXINE HCL- calamine plus no touch spray aerosol, spray

Premier Brands of America Inc.

Premier Solutions Calamine Plus Spray

Active ingredient

Calamine 8% Pramoxine HCl 1%

Purpose

Skin protectant External analgesic

Uses

temporarily relieves pain and itching associated with:

- insect bites
- rashes
- minor skin irritations
- minor cuts
- dries the oozing and weeping of poison ivy, poison oak and poison sumac

Warnings

For external use only.

Flammable:

Do not use while smoking or near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F. Intentional misuse by deliberately concentrating and inhailing contents can be harmful or fatal.

When using this product

- do not get into eyes
- ask a doctor before using on children under 2 years of age

Stop use and ask a doctor if

- conditions worsens
- symtomps last more than 7 days or clear up and occur again in a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake well before using
- adults and children 2 years of age and older: apply to affected area not more than 3 or 4 times daily
- cleanse the skin with soap and water
- let dry before use
- children under 2 years of age: consult a doctor

Other information

store between 20° to 25°C (68° to 77°F)

Inactive ingredients

benzyl alcohol, camphor, disteardimonium hectorite, fragrance, hydrated silica, isobutane, oleyl alcohol, SD alcohol 40-B, sorbitan trioleate

Questions?

Call 1-866-964-0939

Principal Display Panel

Premier

solutions

NO-RUB CALAMINE

PLUS SPRAY

CALAMINE 8% / SKIN PROTECTANT PRAMOXINE HCL 1% / EXTERNAL ANALGESIC

RELIEVES ITCHING FROM

POISON IVY, OAK & SUMAC, PLUS INSECT BITES

Soothes minor skin irritations & cuts

SHAKE WELL!

NET WT. 4.1 OZ. (116g)



CALAMINE PLUS PRAMOXINE HCL

calamine plus no touch spray aerosol, spray

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:56104-100 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|----------------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675) | FERRIC OXIDE RED | 5 mg in 1 g | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 75 mg in 1 g | |
| PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056) | PRAMOXINE HYDROCHLORIDE | 10 mg in 1 g | |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) | | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | | |
| ISOBUTANE (UNII: BXR49TP611) | | |
| OLEYL ALCOHOL (UNII: 172F2WN8DV) | | |

| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
|--|--|
| SORBITAN TRIOLEATE (UNII: QE6F49RPJ1) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| ALCOHOL (UNII: 3K9958V90M) | |

| Packaging | | | | |
|-----------|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:56104-100- 10 | 116 g in 1 CAN; Type 0: Not a Combination Product | 05/28/2025 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M017 | 05/28/2025 | |
| 3 1 3 | | | |

Labeler - Premier Brands of America Inc. (063849780)

Revised: 5/2025 Premier Brands of America Inc.