

SARNA- pramoxine hydrochloride lotion
Crown Laboratories

Sarna Sensitive

Active ingredient

Pramoxine Hydrochloride 1%

Purpose

External analgesic

Uses

- for the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, minor skin irritations and rashes due to poison ivy, poison oak, or poison sumac

Warnings

For external use only.

Do not use

- in the eyes
- over large areas of the body
- for prolonged periods

When using this product

- avoid contact with eyes
- if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

Stop use and ask a doctor if

- redness, irritation, swelling, or pain persists or increases.

Keep out of reach of children.

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

Directions

- To open, hold cap and turn pump clockwise.
- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: do not use, consult a doctor.

Other information

- store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]

Inactive ingredients

Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Beta-Glucan, C12-18 Alkanoyl Glycerin/Sebacic Acid Copolymer, Caprylyl Glycol, Carbomer, Cetyl Alcohol, Citric Acid, Dimethicone, Ethylhexylglycerin, Glyceryl Stearate, Isopropyl Myristate, Palmitic Acid, PEG-100 Stearate, PEG-8 Stearate, Pentylene Glycol, Saccharide Isomerate, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Citrate, Sodium Hydroxide, Squalane, Stearic Acid, Tocopherol, Water

Sarna Sensitive Principal Display Panel

#1 DERMATOLOGIST RECOMMENDED TOPICAL ANTI-ITCH BRAND

Sarna

Pramoxine Hydrochloride 1%

External Analgesic Lotion

Steroid Free

SENSITIVE

ANTI-ITCH LOTION

- Eases itch associated with minor skin irritations
- Soothes and conditions with Aloe, Squalene, and Jojoba Oil
- Hypoallergenic

NET WT. 7.5fl oz (222 ml)

P12305.01



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SARNA

pramoxine hydrochloride lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0316-0230 |
| 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 |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | |
| SACCHARIDE ISOMERATE (UNII: W8K377W98I) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H) | |
| TOCOPHEROL (UNII: ROZB2556P8) | |
| WATER (UNII: 059QF0KO0R) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| PEG-8 STEARATE (UNII: 2P9L47VI5E) | |
| SQUALANE (UNII: GW89575KF9) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| PALMITIC ACID (UNII: 2V16EO95H1) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| YEAST .BETA.-D-GLUCAN (UNII: 44FQ49X6UN) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0316-0230-57 | 222 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 01/01/2024 | |
| 2 | NDC:0316-0230-12 | 355 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 01/01/2024 | |
| 3 | NDC:0316-0230-25 | 5 mL in 1 PACKET; Type 0: Not a Combination Product | 03/18/2024 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M017 | 01/01/2024 | |

Labeler - Crown Laboratories (119508400)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| Crown Laboratories, Inc. | | 119508400 | manufacture(0316-0230) |

