

**SARNA- pramoxine hydrochloride, menthol lotion**  
**Crown Laboratories, Inc**

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**Sarna Calm + Cool**

***Active Ingredients***

Menthol 0.5%

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 or nose
- over large areas of the body
- for prolonged periods

**When using this product**

- avoid contact with the 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, Butylene Glycol, C12-18 Alkanoyl Glycerin/Sebacic Acid Copolymer, Caprylyl Glycol, Carbomer, Cetyl Alcohol, Dimethicone, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Isopropyl Myristate, Palmitic Acid, PEG-100 Stearate, PEG-8 Stearate, Pentylene Glycol, Sodium Hydroxide, Stearic Acid, Tocopherol, Water

**Questions?**

call 1-833-279-6522

**Sarna Calm + Cool Principal Display Panel**

#1 DERMATOLOGIST RECOMMENDED TOPICAL ANTI-ITCH BRAND

Sarna

Pramoxine Hydrochloride 1%

Menthol 0.5%

External Analgesic Lotion

Steroid Free

CALM + COOL

ANTI-ITCH LOTION

Eases pain and itch associated with insect bites, sunburn, and poison ivy

Infused with Witch Hazel Extract

Cools with Menthol

NET WT. 7.5fl oz (222 ml)

P12288.00

**NEW**



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## **CALM + COOL** **ANTI-ITCH LOTION**

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**SARNA**

pramoxine hydrochloride, menthol lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0316-0234
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PRAMOXINE HYDROCHLORIDE</b> (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1000 mL
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 mg in 1000 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>YEAST .BETA.-D-GLUCAN</b> (UNII: 44FQ49X6UN)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>HAMAMELIS VIRGINIANA LEAF</b> (UNII: T07U1161SV)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>PEG-8 STEARATE</b> (UNII: 2P9L47VI5E)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PALMITIC ACID</b> (UNII: 2V16EO95H1)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-0234-75	222 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/05/2024	
2	NDC:0316-0234-12	355 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/05/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/05/2024	

**Labeler** - Crown Laboratories, Inc (079035945)

## Establishment

Name	Address	ID/FEI	Business Operations
Crown Laboratories, Inc		079035945	manufacture(0316-0234)

## Establishment

Name	Address	ID/FEI	Business Operations
VOYANT BEAUTY, INC.		243547333	manufacture(0316-0234)

Revised: 5/2024

Crown Laboratories, Inc