

**CERAVE DEVELOPED WITH DERMATOLOGISTS ITCH RELIEF MOISTURIZING-
pramoxine hydrochloride lotion
L'Oreal USA Products Inc**

Drug Facts

Active ingredient

Pramoxine hydrochloride 1%

Purpose

External analgesic

Use

For the temporary relief of itching associated with minor skin irritations

Warnings

For external use only

When using this product

do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

Keep out of reach of children.

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

Directions

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: consult a doctor

Inactive ingredients

water, isopropyl myristate, PEG-100 stearate, glyceryl stearate, cetearyl alcohol, cetyl alcohol, glycerin, niacinamide, dimethicone, stearic acid, allantoin, potassium phosphate, ceramide NP, ceramide AP, ceramide EOP, carbomer, zinc citrate, behentrimonium methosulfate, sodium hydroxide, sodium lauroyl lactylate, arginine PCA, myristic acid, sodium PCA, cholesterol, palmitic acid, tasmannia lanceolata fruit extract, phenoxyethanol, dipotassium phosphate, disodium EDTA, alcohol denat., tocopheryl acetate, hydrolyzed hyaluronic acid, xanthan gum, phytosphingosine, polyglyceryl-3 diisostearate, ethylhexylglycerin

Questions?

Toll-Free Number **888-768-2915**

www.cerave.com



The image shows a stylized graphic of a CeraVe product container. The container is primarily white with a large, dark red section on the right side. At the top left, a dark red banner contains the text "VALUE SIZE" in white, uppercase letters. Below this, the CeraVe logo is prominently displayed, with "Cera" in dark blue and "ve" in white on a dark red background, followed by a registered trademark symbol (®). Underneath the logo, the text "DEVELOPED WITH DERMATOLOGISTS" is written in dark blue, uppercase letters. The main product name, "Itch Relief Moisturizing Lotion", is written in large, bold, dark red letters. At the bottom, the active ingredient "1% PRAMOXINE HYDROCHLORIDE" is listed in dark blue, uppercase letters. The entire graphic is framed by a thin green dashed line and a red crosshair in the top right corner.

VALUE SIZE

CeraVe®

DEVELOPED WITH DERMATOLOGISTS

**Itch Relief
Moisturizing
Lotion**

1% PRAMOXINE HYDROCHLORIDE

EXTERNAL ANALGESIC

Moisturizes dry skin

With 3 essential ceramides

Relieves itching associated with:

- Insect bites
- Sunburn
- Poison ivy

STEROID FREE

16 FL OZ (473mL)

3612623780978



VALUE SIZE

CeraVe[®]

DEVELOPED WITH DERMATOLOGISTS

Itch Relief




ITCH RELIEF Moisturizing Lotion

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**National
Eczema
Association**

CeraVe[®] Itch Relief Moisturizing Lotion

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benzethonium methosulfate, sodium hydroxide, sodium lauryl lactylate, arginine PCA, myristic acid, sodium PCA, cholesterol, palmitic acid, phenoxyethanol, dipotassium phosphate, disodium EDTA, tocopheryl acetate, hydrolyzed hyaluronic acid, xanthan gum, phytosphingosine, polyglyceryl-3 diisostearate, ethylhexylglycerin

Questions or comments?

Toll-free number 1-888-768-2915

20215023V04 (CODE F.I.L. V70031320/1)

CeraVe LLC,
New York, NY 10001
Made in USA of US and/or
Imported Ingredients
www.cerave.com

3612623780985

2D
Code



12.

CeraVe® Itch Relief Moisturizing Lotion

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No Print Area

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CERAVE DEVELOPED WITH DERMATOLOGISTS ITCH RELIEF MOISTURIZING

pramoxine hydrochloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-970
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
NIACINAMIDE (UNII: 25X51I8RD4)	
CERAMIDE 3 (UNII: 4370DF050B)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALLANTOIN (UNII: 344S277G0Z)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)
ARGININE PYROGLUTAMATE (UNII: 808T94CEU6)
EDETATE DISODIUM (UNII: 7FLD91C86K)
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)
POTASSIUM PHOSPHATE, DIBASIC (UNII: CI71S98N1Z)
ZINC CITRATE (UNII: K72I3DEX9B)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)
CHOLESTEROL (UNII: 97C5T2UQ7J)
MYRISTIC ACID (UNII: 0I3V7S25AW)
PALMITIC ACID (UNII: 2V16EO95H1)
HYALURONIC ACID (UNII: S270N0TRQY)
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-970-01	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/17/2017	
2	NDC:49967-970-02	15 in 1 TRAY	08/17/2017	
2		29.6 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:49967-970-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	
4	NDC:49967-970-04	562 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	08/17/2017	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
L'OREAL USA PRODUCTS, INC		624244349	manufacture(49967-970) , pack(49967-970)

Establishment

Name	Address	ID/FEI	Business Operations
L'Oreal USA, Inc.		960317444	manufacture(49967-970) , pack(49967-970)

Establishment

Name	Address	ID/FEI	Business Operations
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Accupac, LLC

061595175

manufacture(49967-970)

Revised: 12/2023

L'Oreal USA Products Inc