CERAVE DEVELOPED WITH DERMATOLOGISTS ITCH RELIEF MOISTURIZING- pramoxine hydrochloride cream
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

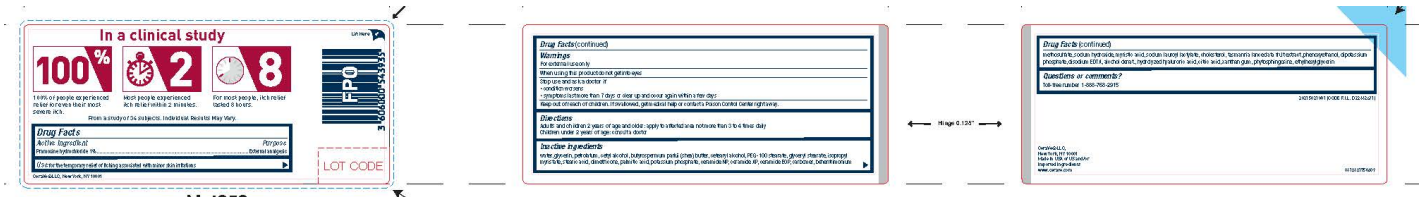
Children under 2 years of age: consult a doctor.

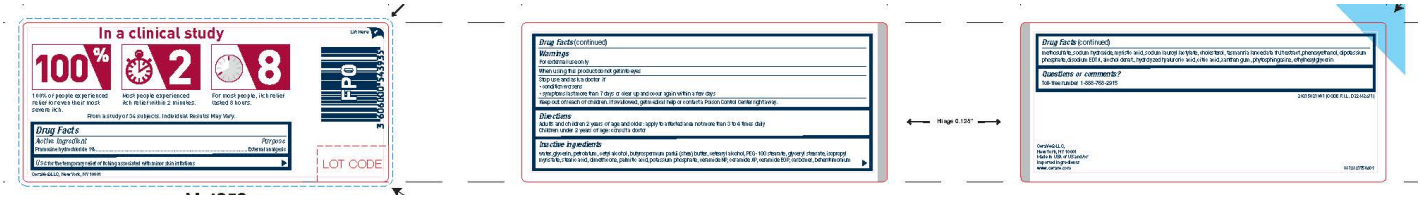
Inactive ingredients

water, glycerin, petrolatum, cetyl alcohol, butyrospermum parkii (shea) butter, cetearyl alcohol, PEG-100 stearate, glyceryl stearate, isopropyl myristate, stearic acid, dimethicone, palmitic acid, potassium phosphate, ceramide NP, ceramide AP, ceramide EOP, carbomer, behentrimonium methosulfate, sodium hydroxide, myristic acid, sodium lauroyl lactylate, cholesterol, tasmannia lanceolata fruit extract, phenoxyethanol, dipotassium phosphate, disodium EDTA, alcohol denat., hydrolyzed hyaluronic acid, citric acid, xanthan gum, hytosphingosine, ethylhexylglycerin

Questions or comments?

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





CERAVE DEVELOPED WITH DERMATOLOGISTS ITCH RELIEF MOISTURIZING

pramoxine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49967-512
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SHEA BUTTER (UNII: K49155WL9Y)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PALMITIC ACID (UNII: 2V16EO95H1)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
CERAMIDE 3 (UNII: 4370DF050B)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALCOHOL (UNII: 3K9958V90M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
POTASSIUM PHOSPHATE, DIBASIC (UNII: CI71S98N1Z)	
TASMANNIA LANCEOLATA FRUIT (UNII: PNT2HDL13Q)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
HYALURONIC ACID (UNII: S270N0TRQY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-512-01	340 g in 1 JAR; Type 0: Not a Combination Product	09/18/2017	
2	NDC:49967-512-02	453.6 g in 1 JAR; Type 0: Not a Combination Product	09/18/2017	
3	NDC:49967-512-03	538.6 g in 1 JAR; Type 0: Not a Combination Product	09/18/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/18/2017	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
Accupac, Inc.		071609663	MANUFACTURE(49967-512)

Revised: 12/2023 L'Oreal USA Products Inc