

**CERAVE DEVELOPED WITH DERMATOLOGISTS THERAPEUTIC HAND-
dimethicone cream
L'Oreal USA Products Inc**

Drug Facts

Active ingredient

Dimethicone 1%

Purpose

Skin protectant

Use

helps prevent and temporarily protects chafed, chapped or cracked skin

Warnings

For external use only

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

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

Keep out of reach of children.

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

Directions

apply as needed




Inactive Ingredients

water, cyclopentasiloxane, aluminum/magnesium hydroxide stearate, cyclohexasiloxane, niacinamide, sodium chloride, polyglyceryl-4 isostearate, cetyl PEG/PPG-10/1 dimethicone, hexyl laurate, phenoxyethanol, ceramide NP, ceramide AP, ceramide EOP, carbomer, methylparaben, sodium lauroyl lactylate, cholesterol, Propylparaben, hydrolyzed hyaluronic acid, phytosphingosine, xanthan gum, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate

Questions or comments?

Toll-free number **1-888-768-2915**

www.cerave.com

 <p>DEVELOPED WITH DERMATOLOGISTS</p> <h1>Therapeutic Hand Cream</h1> <p>DIMETHICONE SKIN PROTECTANT</p> <p>Moisturizes & helps restore the protective skin barrier</p> <p>Helps prevent & temporarily protects chafed, chapped, or cracked skin</p> <p>With 3 essential ceramides, niacinamide & hyaluronic acid</p> <p>NON-GREASY TEXTURE</p> <p>Net Wt. 3 OZ (85 g)</p> 	<table border="1"> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <th><i>Active ingredient</i></th> <th><i>Purpose</i></th> </tr> <tr> <td>Dimethicone 1%</td> <td>Skin protectant</td> </tr> <tr> <th colspan="2"><i>Use</i></th> </tr> <tr> <td colspan="2">helps prevent and temporarily protects chafed, chapped or cracked skin</td> </tr> <tr> <th colspan="2"><i>Warnings</i></th> </tr> <tr> <td colspan="2">For external use only</td> </tr> <tr> <td colspan="2">Do not use on - deeper puncture wounds - animal bites - serious burns</td> </tr> <tr> <td colspan="2">When using this product do not get into eyes</td> </tr> <tr> <td colspan="2">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</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <th colspan="2"><i>Directions</i></th> </tr> <tr> <td colspan="2">apply as needed</td> </tr> <tr> <th colspan="2"><i>Inactive ingredients</i></th> </tr> <tr> <td colspan="2">water, cyclopentasiloxane, aluminum/magnesium hydroxide stearate, cyclohexasiloxane, niacinamide, sodium chloride, polyglyceryl-4 isostearate, cetyl PEG/PPG-10/1 dimethicone, hexyl laurate, phenoxyethanol, ceramide NP, ceramide AP, ceramide EOP, carbomer, methylparaben, sodium lauroyl lactylate, cholesterol, propylparaben, hydrolyzed hyaluronic acid, phytosphingosine, xanthan gum, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate</td> </tr> <tr> <th colspan="2"><i>Questions or comments?</i></th> </tr> <tr> <td colspan="2">Toll-free number 1-888-768-2915</td> </tr> </table> <div style="text-align: right;">  <p>3 606000 582132</p> <p>2021902901 (CODE F.L.L. 008572671) 841262245891</p> </div> <p>CeraVe LLC, New York, NY 10001 Made in USA of US and/or Imported Ingredients www.cerave.com</p>	Drug Facts		<i>Active ingredient</i>	<i>Purpose</i>	Dimethicone 1%	Skin protectant	<i>Use</i>		helps prevent and temporarily protects chafed, chapped or cracked skin		<i>Warnings</i>		For external use only		Do not use on - deeper puncture wounds - animal bites - serious burns		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		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		<i>Directions</i>		apply as needed		<i>Inactive ingredients</i>		water, cyclopentasiloxane, aluminum/magnesium hydroxide stearate, cyclohexasiloxane, niacinamide, sodium chloride, polyglyceryl-4 isostearate, cetyl PEG/PPG-10/1 dimethicone, hexyl laurate, phenoxyethanol, ceramide NP, ceramide AP, ceramide EOP, carbomer, methylparaben, sodium lauroyl lactylate, cholesterol, propylparaben, hydrolyzed hyaluronic acid, phytosphingosine, xanthan gum, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate		<i>Questions or comments?</i>		Toll-free number 1-888-768-2915	
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Moisturizes & helps restore the protective skin barrier

Helps prevent & temporarily protects chafed, chapped, or cracked skin

With 3 essential ceramides, niacinamide & hyaluronic acid

NON-GREASY TEXTURE

Net Wt. 3 OZ (85 g)

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

20219029W1
CODE F.L.L. D08572671
811262345891

CERAVE DEVELOPED WITH DERMATOLOGISTS THERAPEUTIC HAND

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-925
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
NIACINAMIDE (UNII: 25X5118RD4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
CERAMIDE 3 (UNII: 4370DF050B)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
HYALURONIC ACID (UNII: S270N0TRQY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-925-01	1 in 1 CARTON	12/12/2017	12/01/2023
1		85 g in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-925-02	5 g in 1 TUBE; Type 0: Not a Combination Product	12/12/2017	12/01/2023
3	NDC:49967-925-03	1 in 1 CARTON	12/12/2017	
3		85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	12/12/2017	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment			
Name	Address	ID/FEI	Business Operations
L'Oreal USA Products, Inc.		624244349	MANUFACTURE(49967-925) , pack(49967-925)

Establishment			
Name	Address	ID/FEI	Business Operations
Accupac, LLC		071609663	manufacture(49967-925)

Revised: 12/2023

L'Oreal USA Products Inc