

**CERAVE DEVELOPED WITH DERMATOLOGISTS HYDRATING SUNSCREEN SPF 50
FACE LIGHTWEIGHT, NON-GREASY FEEL 3 ESSENTIAL CERAMIDES NIACINAMIDE
MINERAL- titanium dioxide and zinc oxide lotion
L'Oreal USA Products Inc**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients

Titanium dioxide 9%

Zinc oxide 7%

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use

on damaged or broken skin

Stop use and ask a doctor if

rash occurs

Keep out of reach of children.

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

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m.-2p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses
 - children under 6 months of age: Ask a doctor

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

water, glycerin, C12-15 alkyl benzoate, dimethicone, isododecane, styrene/acrylates copolymer, glyceryl stearate, butyloctyl salicylate, dicaprylyl carbonate, propanediol, stearic acid, aluminum hydroxide, PEG-100 stearate, sorbitan stearate, niacinamide, PEG-8 laurate, ceramide NP, ceramide AP, ceramide EOP, sorbitan isostearate, carbomer, cetearyl alcohol, cetareth-20, triethoxycaprylylsilane, dimethiconol, sodium citrate, sodium lauroyl lactylate, sodium dodecylbenzenesulfonate, myristic acid, sodium hyaluronate, cholesterol, palmitic acid, phenoxyethanol, chlorphenesin, tocopherol, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, caprylyl glycol, citric acid, panthenol, xanthan gum, phytosphingosine, polyhydroxystearic acid, polysorbate 60, ethylhexylglycerin

<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Titanium dioxide 9%</td> <td>Sunscreen</td> </tr> <tr> <td>Zinc oxide 7%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> • helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun <p>Warnings</p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product, keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <p>For sunscreen use:</p> <ul style="list-style-type: none"> • apply liberally 15 minutes before sun exposure • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating • Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> • limit time in the sun, especially from 10 a.m. – 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses • children under 6 months of age: Ask a doctor <p>Other information</p> <ul style="list-style-type: none"> • protect the product in this container from excessive heat and direct sun <p>Inactive ingredients</p> <p>water, glycerin, C12-15 alkyl benzoate, dimethicone, isododecane, styrene/acrylates copolymer, glyceryl stearate, butyloctyl salicylate, dicaprylyl carbonate, propanediol, stearic acid, aluminum hydroxide, PEG-100 stearate, sorbitan stearate, niacinamide, PEG-8 laurate, ceramide NP, ceramide AP, ceramide EOP, sorbitan isostearate, carbomer, cetearyl alcohol, cetareth-20, triethoxycaprylylsilane, dimethiconol, sodium citrate, sodium lauroyl lactylate, sodium dodecylbenzenesulfonate, myristic acid, sodium hyaluronate, cholesterol, palmitic acid, phenoxyethanol, chlorphenesin, tocopherol, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, caprylyl glycol, citric acid, panthenol, xanthan gum, phytosphingosine, polyhydroxystearic acid, polysorbate 60, ethylhexylglycerin</p> <p>Questions or comments? Toll-free number 1-888-768-2915</p>	Active ingredients	Purpose	Titanium dioxide 9%	Sunscreen	Zinc oxide 7%	Sunscreen	<p>CeraVe DEVELOPED WITH DERMATOLOGISTS</p> <p>MINERAL SUNSCREEN</p> <p>BROAD SPECTRUM SPF 50</p> <p>Hydrating Sunscreen</p> <p>50 FACE</p> <p>RECOMMENDED</p> <p>SKIN CANCER FOUNDATION</p> <p>DAILY USE</p> <p>CeraVe® LLC, New York, NY 10001 Made in USA of US and/or Imported Ingredients www.cerave.com</p> <p>3612621047691</p>	<p>NEW</p> <p>CeraVe DEVELOPED WITH DERMATOLOGISTS</p> <p>Hydrating Sunscreen</p> <p>BROAD SPECTRUM SPF 50</p> <p>50 FACE</p> <p>Lightweight, non-greasy feel</p> <p>3 essential ceramides & niacinamide</p> <p>MINERAL SUNSCREEN</p> <p>ACCEPTED</p> <p>NATIONAL ECZEMA ASSOCIATION</p> <p>2.5 FL OZ (75 ml)</p>	<p>Developed with dermatologists, its formula – with 3 essential ceramides – helps restore and maintain the protective skin barrier.</p> <p> Broad Spectrum Protection Helps protect your skin against harmful UVA and UVB rays</p> <p> 100% Mineral Sun Filters Reflects and blocks the sun's damaging rays</p> <p> Lightweight & Oil Free Won't clog pores</p> <p> Niacinamide Helps calm skin</p>
Active ingredients	Purpose								
Titanium dioxide 9%	Sunscreen								
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CERAVE DEVELOPED WITH DERMATOLOGISTS HYDRATING SUNSCREEN SPF 50 FACE LIGHTWEIGHT, NON-GREASY FEEL 3 ESSENTIAL CERAMIDES NIACINAMIDE MINERAL titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-959
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	90 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
PROPANEDIOL (UNII: 5965N8W85T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
CERAMIDE NP (UNII: 4370DF050B)	
CERAMIDE AP (UNII: F1X8L2B00J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
MYRISTIC ACID (UNII: 01B3V7S25AW)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
PALMITIC ACID (UNII: 2V16EO95H1)	
phenoxyethanol (UNII: HIE492ZZ3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
PANTHENOL (UNII: WV9CM0067Z)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-959-01	1 in 1 CARTON	02/01/2019	
1		75 mL 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 not final	part352	02/01/2019	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
L'OREAL USA PRODUCTS, INC.		624244349	manufacture(49967-959)

Revised: 12/2018

L'Oreal USA Products Inc