

CERAVE DEVELOPED WITH DERMATOLOGISTS SUNSCREEN BODY BROAD SPECTRUM SPF 30- titanium dioxide, 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 3.67%

Zinc oxide 3.5%

Purpose

Sunscreen

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

When using this product

keep out of eyes. Rinse with water to remove.

Keep out of reach of children.

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

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
- children under 6 months of age: Ask a doctor

● **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. – 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

Inactive ingredients

Water, Dimethicone, Cetyl Dimethicone, Butyloctyl Salicylate, Trimethylsiloxysilicate, Styrene/Acrylates

Copolymer, Dimethicone PEG-8 Laurate, Polysorbate 60, Ceramide 3, Ceramide 6 II, Ceramide 1, Cholesterol, Phytosphingosine, Trisiloxane, Isohexadecane, Arachidyl Alcohol, Butylene Glycol,

Polyhydroxystearic Acid, Hydrated Silica, PEG-100 Stearate, Glyceryl Stearate, Ascorbic Acid, Avena Sativa (Oat) Kernel Extract, Arachidyl Glucoside, Beeswax, Behenyl Alcohol, Benzyl Alcohol,

Stearic Acid, Bisabolol, Dipotassium Glycyrrhizate, Ethylhexylglycerin, Glycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Pantothenic Acid/Yeast Polypeptide,

PEG-8, Xanthan Gum, Polyaminopropyl Biguanide, Polymethyl Methacrylate, Alumina, Potassium Sorbate, Retinyl Palmitate, Sodium Lauroyl Lactylate, Carbomer, Tocopheryl Acetate, BHT,

Disodium EDTA, Methicone, Methylisothiazolinone, Triethoxycaprylylsilane

Other information

Protect this product from excessive heat and direct sun

Questions?

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

www.CeraVe.com

Glue

Developed with dermatologists, **CeraVe SPF 30 Sunscreen for Body** is like no other sunscreen you've ever experienced.

Enjoy high performance protection from the same zinc oxide trusted by lifeguards and dermatologists, now in a new lightweight formula that spreads easily, dries clear and is suitable for daily use on even the most sensitive skin.

- **INVISIBLE ZINC™** technology uses a revolutionary naturally sourced micro-fine zinc oxide to deliver its unique dry, clear finish for powerful protection from the sun's damaging rays.
- Ceramides help repair and restore the protective skin barrier.

High performance, water resistant, suitable for all skin types. It's perfect for daily use on even the most sensitive skin.

Drug Facts
(Continued)

Inactive Ingredients
Water, Dimethicone, Cetyl Dimethicone, Butylacetyl Salicylate, Trimethylsiloxy-silicate, Styrene/Acrylates Copolymer, Dimethicone PEG-8 Laurate, Polyisobutylate 60, Ceramide 3, Ceramide 6 II, Ceramide 1, Cholesterol, Phytosphingosine, Trisiloxane, Isohexadecane, Arachidyl Alcohol, Butylene Glycol, Polyhydroxystearic Acid, Hydrated Silica, PEG-100 Stearate, Glyceryl Stearate, Ascorbic Acid, Avena Sativa (Oat) Kernel Extract, Arachidyl Glucoside, Beeswax, Behenyl Alcohol, Benzyl Alcohol, Stearic Acid, Bisabolol, Dipotassium Glycyrrhizate, Ethylhexylglycerin, Glycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Pantothenic Acid/Yeast Polypeptide, PEG-8, Xanthan Gum, Polyaminopropyl Biguanide, Polymethyl Methacrylate, Alumina, Potassium Sorbate, Retinyl Palmitate, Sodium Lauroyl Laurylate, Carbomer, Tocopheryl Acetate, BHT, Disodium EDTA, Methicone, Methylisothiazolinone, Triethoxycaprylsilane

Other Information
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Questions?
Toll-free number 1-888-768-2915
www.CeraVe.com

CeraVe® LLC,
New York, NY 10001
Made in USA
www.cerave.com
Questions or comments?
1-888-768-2915
5000000002416

NEW

CeraVe®
DEVELOPED WITH DERMATOLOGISTS

Sunscreen
BROAD SPECTRUM SPF 30

BODY LOTION **SPF 30**

InVisibleZinc™
Lightweight and oil-free
Water resistant (40 minutes)
With ceramides

Net Wt. 3.5 OZ (99 g)

Drug Facts

Active Ingredients Purpose
Titanium Dioxide 3.67%.....Sunscreen
Zinc Oxide 3.5%.....Sunscreen

Uses
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• 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

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• Children under 6 months: Ask a doctor
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• Wear long-sleeved shirts, pants, hats and sunglasses



SPECTRUM SPF 30

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	36.7 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	35.0 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHICONE PEG-8 LAURATE (UNII: 72MF9C2A18)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CERAMIDE NP (UNII: 4370DF050B)	
CERAMIDE AP (UNII: F1X8L2B00J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
ISOHEXADECANE (UNII: 918X10UF1E)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
OAT (UNII: Z6J799EAJK)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
DOCOSANOL (UNII: 9G1OE216XY)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LEVOMENOL (UNII: 24WE03BX2T)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
PANTOTHENIC ACID (UNII: 19F5HK2737)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
XANTHAN GUM (UNII: TTV12P4NEE)
POLIHEXANIDE (UNII: 322U039GMF)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
ALUMINUM OXIDE (UNII: LM26O6933)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
EDETATE DISODIUM (UNII: 7FLD91C86K)
METHICONE (20 CST) (UNII: 6777U11MKT)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-901-01	1 in 1 CARTON	01/04/2018	
1		99 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 final	part352	01/04/2018	

Labeler - L'Oreal USA Products Inc. (002136794)

Establishment			
Name	Address	ID/FEI	Business Operations
L'Oreal USA Products, Inc.		624244349	MANUFACTURE(49967-901)