

CERAVE SUNSCREEN BROAD SPECTRUM SPF 50 FACE- titanium dioxide, zinc oxide lotion
Valeant Pharmaceuticals North America LLC

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.

CeraVe®
Face Lotion
Sunscreen Broad Spectrum SPF 50

Drug Facts

Active Ingredients	Purpose
Titanium Dioxide 4.9%	Sunscreen
Zinc Oxide 4.7%	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
- **When using this product** keep out of eyes. Rinse with water to remove
- **Stop use and ask a doctor** if rash occurs
- **Keep out of reach of children.** If product is 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: 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, butyloctyl salicylate, cetyl dimethicone, dimethicone, styrene/acrylates copolymer, trimethylsiloxysilicate, dimethicone PEG-8 laurate, isohexadecane, butylene glycol, polysorbate 60, trisiloxane, arachidyl alcohol, polyhydroxystearic acid, hydrated silica, ceramide 3, ceramide 6-II, ceramide 1, niacinamide, cholesterol, phytosphingosine, 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 **(800) 321-4576**

www.cerave.com

PRINCIPAL DISPLAY PANEL - 2.0 oz SPF 50 Face Lotion

CeraVe[®]

DEVELOPED WITH DERMATOLOGISTS

Sunscreen

BROAD SPECTRUM SPF 50

FACE LOTION

SPF 50

InVisibleZinc[®]

Lightweight and oil-free

Water resistant (40 minutes)

With ceramides and niacinamide

Net Wt. 2.0 OZ (56 g)

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	2.744 g in 56 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	2.632 g in 56 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE PEG-8 LAURATE (UNII: 72MF9C2A18)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CERAMIDE 3 (UNII: 4370DF050B)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
NIACINAMIDE (UNII: 25X51I8RD4)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
OAT (UNII: Z6J799EAJK)	
ARACHIDYL GLUCOSIDE (UNII: 6JVVW35JOOJ)	
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)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLIHEXANIDE (UNII: 322U039GMF)	
ALUMINUM OXIDE (UNII: LM26O6933)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0187-2205-01	56 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0187-2205-02	5 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	12/25/2012	

Labeler - Valeant Pharmaceuticals North America LLC (042230623)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	MANUFACTURE(0187-2205)

Revised: 10/2015

Valeant Pharmaceuticals North America LLC