

CERAVE SUNSCREEN BROAD SPECTRUM SPF 30 BODY- 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®

**Sunscreen Broad Spectrum SPF 30
BODY LOTION**

Drug Facts

<i>Active Ingredient</i>	<i>Purpose</i>
Titanium Dioxide 3.67%	Sunscreen
Zinc Oxide 3.5%	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: 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 800-321-4576

www.CeraVe.com

PRINCIPAL DISPLAY PANEL - 3.5 oz. Tube

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)

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)

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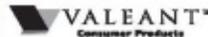
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Distributed by:
Valeant Consumer Products,
a division of Valeant Pharmaceuticals
North America LLC
Bridgewater, NJ 08807
VNT-3160DY-25 05/13

Net Wt. 3.5 OZ (99 g)



titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0187-2209
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)	
GLICYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
PANTOTHENIC ACID (UNII: 19F5HK2737)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

XANTHAN GUM (UNII: TTV12P4NEE)
POLYHEXANIDE (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)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0187-2209-01	1 in 1 CARTON	01/01/2014	
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	01/01/2014	

Labeler - Valeant Pharmaceuticals North America LLC (042230623)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	MANUFACTURE(0187-2209)

Revised: 1/2014

Valeant Pharmaceuticals North America LLC