

ULTIMATE PROTECTION SPF28- zinc oxide, titanium dioxide cream
Face Reality Skin Care, LLC

Ultimate Protection SPF 28

Drug Facts

Active Ingredient(s):

11.6% Zinc Oxide, 0.67% Titanium Dioxide

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.

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

Directions:

• Apply liberally 15 minutes before sun exposure. • Use a water resistant sunscreen if swimming or sweating. • Reapply at least every 2 hours. • 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 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-sleeve shirts, pants, hats and sunglasses. • Children under 6 months: Ask a doctor.

Sun Protection Measures.

Other Information:

Protect this product from excessive heat and direct sun.

Inactive Ingredients:

Aqua (Water), Caprylic/Capric Triglyceride, Cetyl Alcohol, Cetearyl Glucoside, Coco-Caprylate/Caprates, Polysorbate 60, Glycerin, Squalane, Polyglyceryl-6 Polyricinoleate, Isononyl Isononanoate, Magnesium Aluminum Silicate, Xanthan Gum, Glyceryl Isostearate, Polyhydroxystearic Acid, Alumina, Tocopherol (D-alpha), Helianthus Annuus (Sunflower) Seed Oil, Aloe Barbadensis Leaf Juice Powder*, Dimethicone, Fructooligosaccharides (D-Beta), Allantoin, Potassium Sorbate, Trisodium Ethylenediamine Disuccinate, Citric Acid, Populus Temuloides Bark Extract, Leuconostoc/Radish Root Ferment Filtrate, Dicaprylyl Ether, 1,2 Hexanediol, Caprylyl Glycol, Gluconolactone, Lonicera Caprifolium (Honeysuckle) Flower Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Tropolone

QUESTIONS

1.866.477.3077

Package Labeling:

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facerealityskincare.com
Dist. by: Face Reality, Inc.
Danville, CA 94526



ultimate protection
spf 28
broad spectrum sunscreen
for acne-prone skin

2.0 FL OZ (66 g)

ULTIMATE PROTECTION SPF28

zinc oxide, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70707-619
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.116 g in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.0067 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	

COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)
POLYSORBATE 60 (UNII: CAL22UVI4M)
GLYCERIN (UNII: PDC6A3C0OX)
SQUALANE (UNII: GW89575KF9)
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
XANTHAN GUM (UNII: TTV12P4NEE)
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)
ALUMINUM OXIDE (UNII: LMI26O6933)
TOCOPHEROL (UNII: R0ZB2556P8)
SUNFLOWER OIL (UNII: 3W1JG795YI)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
ALLANTOIN (UNII: 344S277G0Z)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)
DICAPRYLYL ETHER (UNII: 77JZM5516Z)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
GLUCONOLACTONE (UNII: WQ29KQ9POT)
TROPOLONE (UNII: 7L6DL16P1T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70707-619-01	66 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/01/2014	

Labeler - Face Reality Skin Care, LLC (602958071)

Registrant - Face Reality Skin Care, LLC (602958071)

Establishment

Name	Address	ID/FEI	Business Operations
Island Kinetics d.b.a. CoValence Laboratories		959735002	manufacture(70707-619)