

LIFECCELL BROAD SPECTRUM SPF 30 BB CREAM- octinoxate and zinc oxide cream
Prime Enterprises 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.

Lifecell BB Cream Broad Spectrum SPF 30

Active Ingredients

Octinoxate 3%

Zinc Oxide 3%

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

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- ***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 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-sleeved shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Bentonite, Camellia Sinensis (Green Tea) Leaf Extract, Caramel, Cetyl

Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Cholecalciferol, Cyclohexasiloxane, Cyclopentasiloxane, Disodium EDTA, DMDM Hydantoin, Hexyl Laurate, Hydrogenated Castor Oil, Iron Oxides, Isocetyl Stearate, Melanin, Octyl Stearate, Polyethylene, Polyglyceryl-4 Isostearate, Propylene Glycol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Silica, Sodium Chloride, Titanium Dioxide, Tocopheryl Acetate, Triethoxycaprylylsilane, Water

Other Information

- protect this product from excessive heat and direct sun

Questions or comments?

- Call toll free 1-866-978-5848

Lifecell BB Cream Broad Spectrum SPF 30

Drug Facts

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DISTRIBUTED BY LIFECELL®
HOLLYWOOD, FL 33020
MANUFACTURED IN USA
PLEASE RECYCLE

Hypoallergenic
Dermatologist Tested




**HYDRATING
ANTIOXIDANT
BB CREAM**

Broad Spectrum
SPF 30

Water Resistant
(80 Minutes).



MEDIUM

1.7 FL OZ (50mL)

Dermatologist Tested
Hypoallergenic

**YOUTHFUL SKIN
AT ANY AGE**

LifeCell® BB Cream provides all-day hydration, Broad Spectrum SPF 30 protection, and enough coverage to reduce the appearance of imperfections.

SUITABLE FOR
ALL SKIN TYPES

www.lifecellskincare.com

LIFECELL BROAD SPECTRUM SPF 30 BB CREAM

octinoxate and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0193
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	29.4 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	29.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALMOND OIL (UNII: 66YXD4DKO9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
BENTONITE (UNII: A3N5ZCN45C)	
CARAMEL (UNII: T9D99G2B1R)	
CETYL DIMETHICONE 45 (UNII: IK315POC44)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
MELANIN SYNTHETIC (TYROSINE, PEROXIDE) (UNII: O0CV1RMR44)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
OCTYL STEARATE (UNII: 772Y4UFC8B)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0193-3	50 mL in 1 TUBE; Type 0: Not a Combination Product	08/01/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/01/2013	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0193) , manufacture(58443-0193) , label(58443-0193)

Revised: 1/2020

Prime Enterprises Inc.