

DARK CC CREME BROAD SPECTRUM SPF 15 JAFRA- zinc oxide cream
Jafra Cosmetics International

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.

Dark CC Creme Broad Spectrum SPF 15

Active

ingredients	Purpose
Zinc Oxide 6.8%	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

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs

- **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.

Directions

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply 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 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

Water/Aqua, Cyclopentasiloxane, PEG/PPG-18/18 Dimethicone, Cyclomethicone, Caprylic Capric Triglyceride, Polyhydroxystearic Acid, Propanediol, Titanium Dioxide/CI 77891, Triethoxycaprylsilane, Dimethicone, PEG-10 Dimethicone, Disteardimonium Hectorite, Boron Nitride, Iron Oxides/ CI 77491/CI 77492/CI 77499, Methicone, Glycerin, Sodium Chloride, Sodium Dehydroacetate, DMDM Hydantoin, Palmitic Acid, Disodium EDTA, Dextrin, Palmitate, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Cucumis Sativus Extract, Glycyrrhiza Glabra Extract, Tocopherol

Dark

Jafra

CC Creme

Broad Spectrum SPF 15

30 ml / 1 FL OZ (US)

LIGHT

Drug Facts

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Drug Facts (continued)

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Drug Facts (continued)

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Other information

- protect this product from excessive heat and direct sun

JAFRA

To use: Apply to clean face and blend with finger tips. Clinically, Allergy, Irritancy and Dermatologist tested.

CC CRÈME
BROAD SPECTRUM
SPF 15

30 mL/1 FL OZ (US)

DARK CC CREME BROAD SPECTRUM SPF 15 JAFRA

zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68828-237

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	6.8 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PROPANEDIOL (UNII: 5965N8W85T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PALMITIC ACID (UNII: 2V16EO95HI)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PEG-4 LAURATE (UNII: AYP4VM3N1Z)	
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)	
CUCUMBER (UNII: YY7C30VXJT)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-237-02	1 in 1 BOX	07/13/2015	
1	NDC:68828-237-01	30 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part352	07/13/2015	
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Labeler - Jafra Cosmetics International (041676479)

Registrant - Jafra Cosmetics International (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V		8 14732061	manufacture(68828-237)

Revised: 6/2019

Jafra Cosmetics International