LONG WEAR MAKEUP BROAD SPECTRUM SPF 20 NUDE JAFRA- octis alate, 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.

Long Wear Makeup Broad Spectrum SPF 20 Nude

Active

Ingredients Purpose

Octisalate 3% Sunscreen

Zinc Oxide 6.8% Sunscreen

Uses

- ©helps prevent suburn
- 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

IKeep 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 lif rash occurs

Warnings

- For external use only
- **Do not use** Ion damaged or broken skin
- **When using this product keep** out of eyes. Rinse with water to remove.

Directions

- Dapply 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

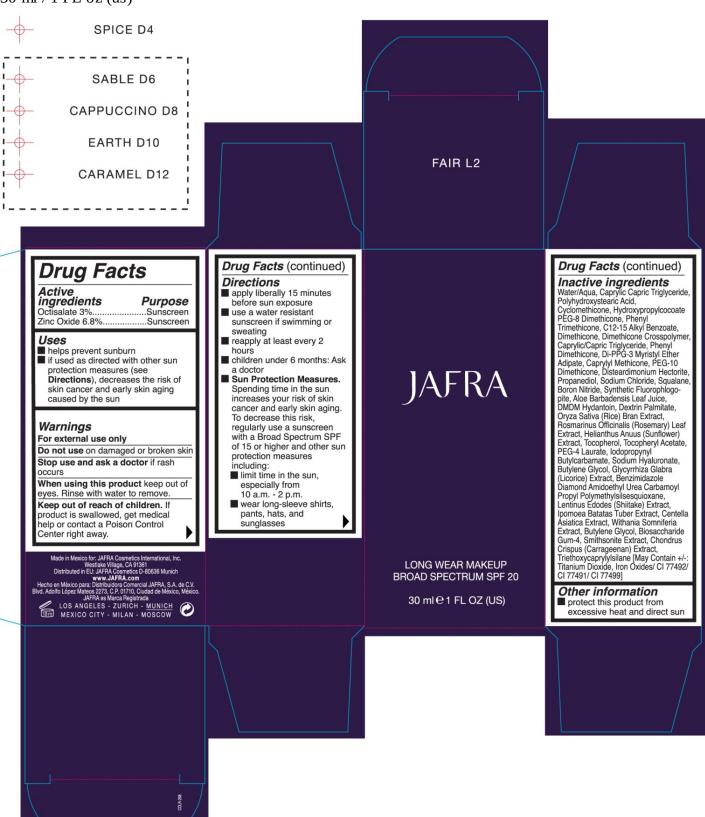
Water/Aqua, Caprylic Capric Triglyceride, Polyhydroxystearic Acid, Cyclomethicone, Hydroxypropylcocoate PEG-8 Dimethicone, Phenyl Triemthicone, C12-15 Alkyl Benzoate, Dimethicone, Dimethicone Crosspolymer, Caprylic/Capric Triglyceride, Phenyl Dimethicone, Di-PPG-3 Myristyl Ether Adipate, Caprylyl Methicone, PEG-10 Dimethicone, Disteardimonium Hectorite, Propanediol, Sodium Chloride, Squalane, Boron Nitride, Synthetic Fluorophlogopite, Aloe Barbadensis Leaf Juice, DMDM Hydantoin, Dextrin Palmitate, Oryza Sativa (Rice) Bran Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Helianthus Anuus (Sunflower) Extract, Tocopherol, Tocopheryl Acetate, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Sodium Hyaluronate, Butylene Glycol, Glycyrrhiza Glabra (Licorice) Extract, Benzimidazole Diamond Amidoethyl Urea Carbamoyl Propyl Polymehtylsilsesquioxane, Lentinus Edodes (shiitake) Extract, Ipomoea Batatas Tuber Extract, Centella Asiatica Extract, Withania Somniferia Extract, Butylene Glycol, Biosaccharide Gum-4, Smithsonite Extact, Chondrus Crispus (Carrageenan) Extract, Triethoxycaprylylsilane [May Containt +/-: Titanium

Dioxide, Iron Oxides/ CI 77492/ CI 77491/ CI 77499]

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Long Wear Makeup Broad Spectrum SPF 20

30 ml / 1 FL oz (us)



LONG WEAR MAKEUP BROAD SPECTRUM SPF 20 NUDE JAFRA

octisalate, zinc oxide cream

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68828-263

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	3 g in 100 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	6.8 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strengt
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
HYDRO XYPRO PYLCO CO ATE PEG-8 DIMETHICO NE (UNII: 8 TE 0 BZU36 S)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NOJ4R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
DIMETHICO NE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLO PENTASILO XANE) (UNII: UF7620L1W6)	
DI-PPG-3 MYRISTYL ETHER ADIPATE (UNII: T32481VTXW)	
CAPRYLYL TRISILO XANE (UNII: Q95M2P1KJL)	
PEG-10 DIMETHICO NE (600 CST) (UNII: 8PR7V1SVM0)	
DISTEARDIMO NIUM HECTO RITE (UNII: X687XDK09L)	
PROPANEDIOL (UNII: 5965N8W85T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SQUALANE (UNII: GW89575KF9)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)	
RICE BRAN (UNII: R60 QEP13IC)	
ROSEMARY (UNII: IJ67X351P9)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
TOCOPHEROL (UNII: R0 ZB2556P8)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-4 LAURATE (UNII: AYF4VM3N1Z)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
LICORICE (UNII: 61ZBX54883)	
LENTINULA EDO DES MYCELIUM (UNII: CU2S39TB8O)	

CENTELLA ASIATICA (UNII: 7M867G6T1U)	
WITHANIA SOMNIFERA LEAF (UNII: J337CNM3CW)	
BIO SACCHARIDE GUM-4 (UNII: 9XRL057X90)	
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)	
TRIETHO XYCAPRYL YLSILANE (UNII: LDC331P08E)	

Other Ingredients				
Ingredient Kind	Ingredient Name	Quantity		
May contain	TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
May contain	FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
May contain	FERRIC O XIDE RED (UNII: 1K09F3G675)			
May contain	FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)			

	Packaging			
I	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:68828-263-02	1 in 1 BOX	02/21/2017	
	1 NDC:68828-263-01	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
OTC monograph final	part352	0 2/2 1/2 0 17	

Labeler - JAFRA COSMETICS INTERNATIONAL (041676479)

Registrant - JAFRA COSMETICS INTERNATIONAL (041676479)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jafra Manufacturing, S.A. de C.V		814732061	manufacture(68828-263)	

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