

JAFRA LONG WEAR MAKEUP BROAD SPECTRUM SPF 20- octisalate, 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.

JAFRA - Fair - Long Wear Makeup Broad Spectrum SPF 20

Active

Ingredients Purpose

Octisalate 3% Sunscreen

Zinc Oxide 6.82% Sunscree

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

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

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.

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

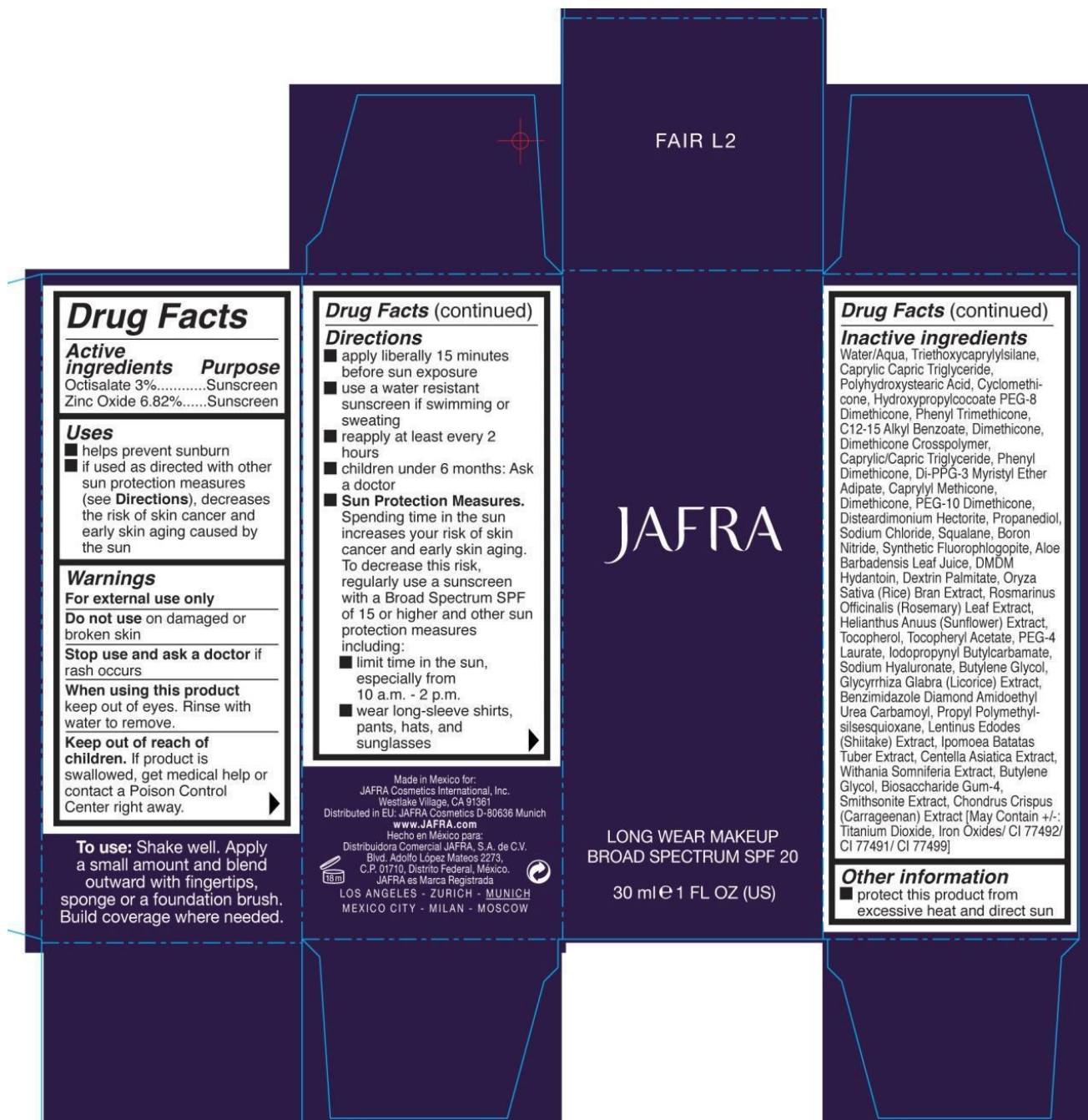
Water/Aqua, Triethoxycaprylylsilane, Caprylic Capric Triglyceride, Polyhydroxystearic Acid, Cyclomethicone, Hydroxypropylcocoate PEG-8 Dimethicone, Phenyl Triemthicone, C12-15 Alkyl Benzoate, Dimethicone, Dimethicone Crosspolymer, Caprylic/Capric Triglyceride, Phenyl Dimethicone, Di-PPG-3 Myristyl Ether Adipate, Caprylyl Methicone, Dimethicone, PEG-10 Dimethicone, Distardimonium Hectorite, Propanediol, Sodium Chloride, Squalane, Boron Nitride, Synthetic Fluorophlogopite, Aloe Barbadosensis 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 [May Containt +/-: Titanium Dioxide, Iron Oxides/ CI 77492/ CI 77491/ CI 77499]

JAFRA

Long Wear Makeup

Broad Spectrum SPF 20

30 ml / 1 FL oz (us)



JAFRA LONG WEAR MAKEUP BROAD SPECTRUM SPF 20

octisalate, zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68828-225 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|--------------------------|------------------|
| Ingredient Name | Basis of Strength | Strength |
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 3 g in 100 mL |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 6.82 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| WATER (UNII: 059QF0K00R) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| CYCLOMETHICONE (UNII: NMQ347994Z) | |
| HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S) | |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R) | |
| C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| DIMETHICONE CROSSPOLYMER (45000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| DI-PPG-3 MYRISTYL ETHER ADIPATE (UNII: T32481VTXW) | |
| CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL) | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SQUALANE (UNII: GW89575KF9) | |
| BORON NITRIDE (UNII: 2U4T60A6YD) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| ICODextrin (UNII: 2NX48Z0A9G) | |
| RICE BRAN (UNII: R60QEP13IC) | |
| ROSEMARY (UNII: IJ67X351P9) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| PEG-4 LAURATE (UNII: AYP4VM3N1Z) | |
| IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) | |
| LENTINULA EDODES MYCELIUM (UNII: CU2S39TB8O) | |
| SWEET POTATO (UNII: M9WGG9Z9GK) | |
| CENTELLA ASIATICA (UNII: 7M867G6T1U) | |
| BIO SACCHARIDE GUM-4 (UNII: 9XRL057X90) | |
| CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:68828-225-02 | 1 in 1 BOX | | |
| 1 | NDC:68828-225-01 | 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 | 07/07/2015 | |

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(68828-225) |

Revised: 7/2015

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