

**RADIANCE FOUNDATION BROAD SPECTRUM SPF 20 - BRONZE JAFRA- octinoxate, 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.*

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**Bronze - Radiance Foundation Broad Spectrum SPF 20**

Octinoxate 3% ..... Sunscreen

Zinc Oxide 6.8% ..... Sunscreen

**Uses**

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**)

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
  
- 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 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

Water/Aqua, Titanium Dioxide, Triethoxycaprylylsilane, Caprylic/Capric Triglyceride, Polyhydroxystearic Acid, Cyclomethicone, Hydroxypropylcocoate PEG-8 Dimethicone, C12-15 Alkyl Benzoate, Phenyl Dimethicone, Phenyl Trimethicone, Cyclopentasiloxane, Dimethicone/Vinyl Dimethicone Crosspolymer, Squalane, Di-PPG-3 Myristyl Ether Adipate Caprylyl Methicone, Dimethicone, PEG-10 Dimethicone, Disteardimonium Hectorite, Boron Nitride, Royal Jelly, Propanediol, Sodium Chloride, DMDM Hydantoin, Dextrin Palmitate, Oryza Sativa (Rice) Bran Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Helianthus Anuus (Sunflower) Extract, Tocopherol, Panthenol, Tocopheryl Acetate, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Withania Somnifera (Winter Cherry) Extract, Nelumbo Nucifera (Lotus) Extract, Biosaccharide Gum-4, Chondrus Crispus (Carrageenan) Extract, Smithsonite Extract, Iron Oxides/CI 77491/CI 77492/CI 77499

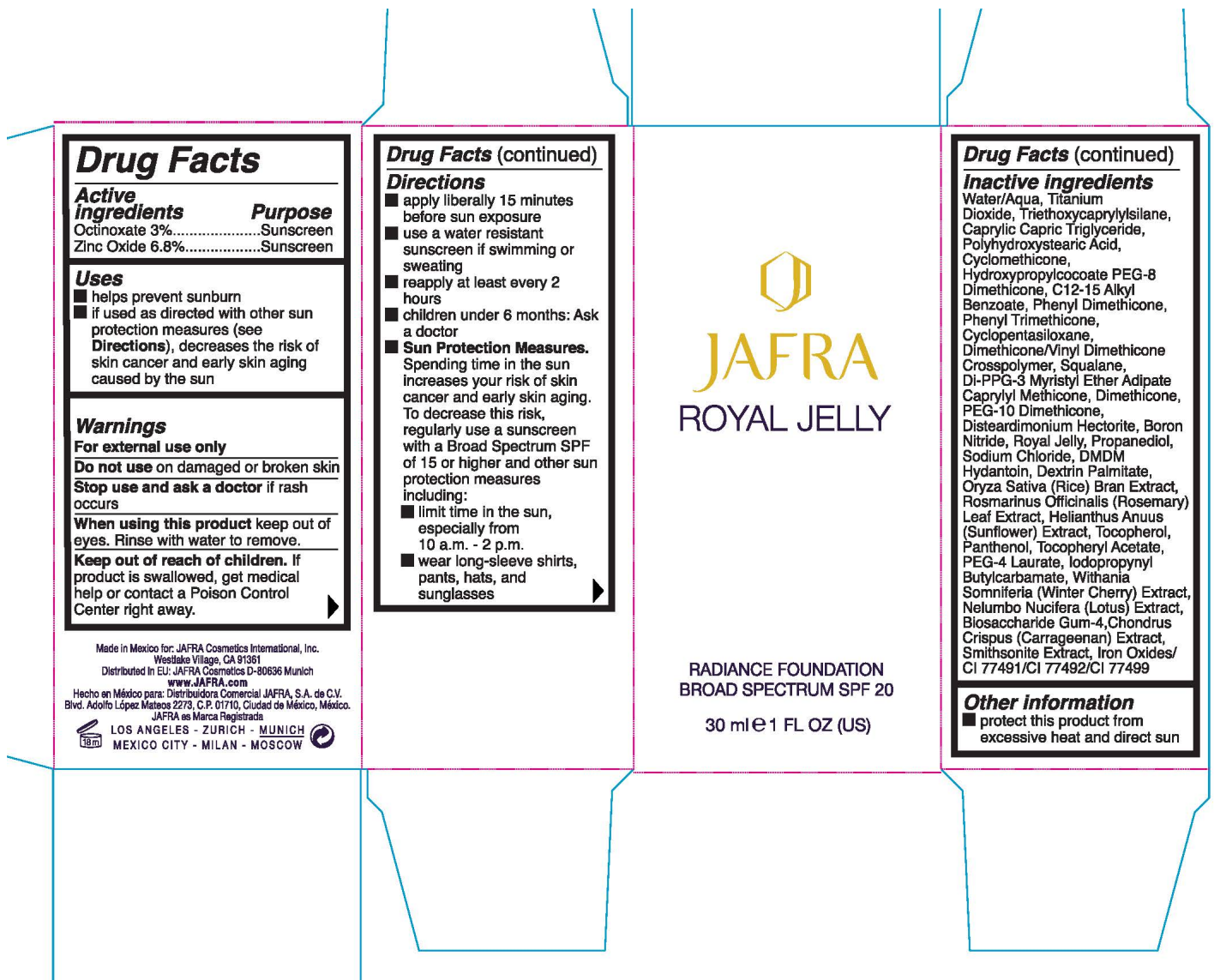
JAFRA

Royal Jelly

Radiance Foundation

Broad Spectrum SPF 20

30 ml 1 FL OZ (US)



## RADIANCE FOUNDATION BROAD SPECTRUM SPF 20 - BRONZE JAFRA

octinoxate, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68828-251
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	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	Strength
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
CYCLOMETHICONE (UNII: NMQ347994Z)
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
SQUALANE (UNII: GW89575KF9)
DI-PPG-3 MYRISTYL ETHER ADIPATE (UNII: T32481VTXW)
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)
DIMETHICONE (UNII: 92RU3N3Y1O)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
BORON NITRIDE (UNII: 2U4T60A6YD)
ROYAL JELLY (UNII: L497I37F0C)
PROPANEDIOL (UNII: 5965N8W85T)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
DMDM HYDANTOIN (UNII: BYR0546TOW)
RICE BRAN (UNII: R60QEP13IC)
ROSEMARY (UNII: IJ67X351P9)
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)
TOCOPHEROL (UNII: R0ZB2556P8)
PANTHENOL (UNII: WV9CM0O67Z)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PEG-4 LAURATE (UNII: AYP4VM3N1Z)
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)
BIOSACCHARIDE GUM-4 (UNII: 9XRL057X90)
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-251-02	1 in 1 BOX	08/11/2015	
1	NDC:68828-251-01	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 mono graph final	part352	08/11/2015	

**Labeler** - JAFRA COSMETICS INTERNATIONAL (041676479)

**Registrant** - JAFRA COSMETICS INTERNATIONAL (041676479)

## Establishment

Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V		8 14732061	manufacture(68828-251)

Revised: 1/2019

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