

**SABLE RADIANCE FOUNDATION BROAD SPECTRUM SPF 20 - TAWNY 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.*

**Sable- 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)

## Drug Facts

### Active Ingredients

Octinoxate 3%.....Sunscreen  
Zinc Oxide 6.8%.....Sunscreen

### Purpose

### 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**

**Stop use and ask a doctor** if rash occurs

**When using this product** keep out of eyes. Rinse with water to remove.

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

Made in Mexico for: JAFRA Cosmetics International, Inc.  
Westlake Village, CA 91381  
Distributed in EU: JAFRA Cosmetics D-90636 Munich  
www.JAFRA.com  
Hecho en México para: Distribuidora Comercial JAFRA, S.A. de C.V.  
Blvd. Adolfo López Mateos 2273, C.P. 01710, Ciudad de México, México.  
JAFRA es Marca Registrada  
LOS ANGELES - ZURICH - MUNICH  
MEXICO CITY - MILAN - MOSCOW

## Drug Facts (continued)

### 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

  
**JAFRA**  
ROYAL JELLY

RADIANCE FOUNDATION  
BROAD SPECTRUM SPF 20

30 ml e 1 FL OZ (US)

## Drug Facts (continued)

### Inactive ingredients

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, Distearidimonium 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 Somniferia (Winter Cherry) Extract, Nelumbo Nucifera (Lotus) Extract, Biosaccharide Gum-4, Chondrus Crispus (Carrageenan) Extract, Smithsonian Extract, Iron Oxides/CI 77491/CI 77492/CI 77499

### Other information

- protect this product from excessive heat and direct sun

## SABLE RADIANCE FOUNDATION BROAD SPECTRUM SPF 20 - TAWNY JAFRA

octinoxate, zinc oxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-260
Route of Administration	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: 059QF0K00R)	

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: 0THF5PCI0R)
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)
BIO SACCCHARIDE GUM-4 (UNII: 9XRL057X90)
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-260-02	1 in 1 BOX	02/21/2017	
1	NDC:68828-260-01	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	02/21/2017	

**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(68828-260)

Revised: 2/2019

JAFRA COSMETICS INTERNATIONAL