

**CC CREME CONCEALER BROAD SPECTRUM SPF 20 JAFRA- avobenzone, homosalate, octisalate, octocrylene 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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**CC Creme Concealer Broad Spectrum SPF 20**

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 5%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 7%	Sunscreen

**Uses**

helps prevent sunburn

if used as directed with other sun protection measures (see **Directions**), decreases the risk of cancer and early skin aging

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.

**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 value 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

**Inactive ingredients**

Caprylic/Capric Triglyceride, Ethylhexyl Palmitate, Diisopropyl Dimer Dilinoleate, Ozokerite, Euphorbia Cerifera (Candelilla) Wax/Candelilla Cera, Bis-Stearyl Dimethicone, Copernicia Cerifera (Carnauba) Wax, Beeswax- /Cera Alba, Ricinus Communis (Castor) Seed Oil, Stearalkonium Hectorite, Propylene Carbonate, Oryza Sativa (Rice) Bran Extract, Aluminum Starch Octenylsuccinate, Lauroyl Lysine, Rosmarinus Officinalis (Rosemary) Leaf Extract, Helianthus Anuus (Sunflower) Extract, Tocopherol, Silica Silylate, Cucumis Sativus Extract, Glycyrrhiza Glabra Extract, Biosaccharide Gum-

4, Chondrus Crispus (Carrageenan) Extract, Water [May Contain +/-: Iron Oxides/CI 77491/CI 77492/CI 77499, Titanium Dioxide/CI 77891]

CC Creme Concealer Broad Spectrum SPF 20

1.8g Net wt. .06 oz

## Drug Facts

### Active ingredients

	<i>Purpose</i>
Avobenzone 3%.....	Sunscreen
Homosalate 5%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Octocrytene 7%.....	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

### 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.

### 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 value 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

### Inactive ingredients

Caprylic/Capric Triglyceride, Ethylhexyl Palmitate, Diisopropyl Dimer Dilinoleate, Ozokerite, Euphorbia Cerifera (Candelilla) Wax/Candelilla Cera, Bis-Stearyl Dimethicone, Copernicia Cerifera (Carnauba) Wax, Beeswax-/Cera Alba, Ricinus Communis (Castor) Seed Oil, Stearalkonium Hectorite, Propylene Carbonate, Oryza Sativa (Rice) Bran Extract, Aluminum Starch Octenylsuccinate, Lauroyl Lysine, Rosmarinus Officinalis (Rosemary) Leaf Extract, Helianthus Anuus (Sunflower) Extract, Tocopherol, Silica Silylate, Cucumis Sativus Extract, Glycyrrhiza Glabra Extract, Biosaccharide Gum-4, Chondrus Crispus (Carrageenan) Extract, Water [May Contain +/-: Iron Oxides/CI 77491/CI 77492/CI 77499, Titanium Dioxide/CI 77891]

### Other information

- protect this product from excessive heat and direct sun



## CC CREME CONCEALER BROAD SPECTRUM SPF 20 JAFRA

avobenzone, homosalate, octisalate, octocrylene cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68828-241
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
CERESIN (UNII: Q1LS2UJO3A)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
WHITE WAX (UNII: 7G1J5DA97F)	
CASTOR OIL (UNII: D5340Y2I9G)	
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
RICE BRAN (UNII: R60QEP13IC)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
LAUROYL LYSINE (UNII: 113171Q70B)	
ROSEMARY (UNII: IJ67X351P9)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CUCUMBER (UNII: YY7C30VXJT)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
BIO SACCHARIDE GUM-4 (UNII: 9XRL057X90)	
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)	
WATER (UNII: 059QF0KO0R)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-241-02	1 in 1 CARTON	08/11/2015	
1	NDC:68828-241-01	1.8 g 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 not 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		814732061	manufacture(68828-241)

