

3-IN-1 FACE MOISTURIZER BROAD SPECTRUM SPF 20- avobenzone, homosalate, octisalate, octocrylene jelly
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.

3-in-1 Face Moisturizer Broad Spectrum SPF 20

Active ingredient Purpose

Avobenzone 3% Sunscreen

Homosalate 10% Sunscreen

Octisalate 5% Sunscreen

Octocrylene 10% 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.

Keep out of reach of children

If product is swallowed, get medical help or contact a poison Control Center right away

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

Stop use and ask a doctor if

rash occurs or irritation develops and lasts.

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 of age: 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 your time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses

Inactive ingredients: Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aluminum Starch Octenylsuccinate, Arachidyl

Alcohol, Arachidyl Glucoside, Arginine, Behenyl Alcohol, Bisabolol, Butylene Glycol, Butyloctyl Salicylate, Butylphenyl Methylpropional (Lilial), Butyrospermum Parkii (Shea) Butter, C13-16 Isoparaffin, Caffeine, Capryloyl Glycerin/Sabacic Acid Copolymer, Cetyl Alcohol, citral, citronellol, Coumarin, Dimethicone, Dipropylene Glycol, Disodium EDTA, Ethylhexyl Methoxycrylene, Ethylhexylglycerin, Fragrance/Parfum, Glycerin, Glyceryl Stearate, Heptyl Undecylenate,

Hydrogenated Lecithin, Lauroyl Lysine, Lecithin, Limonene, Linalool, Maltodextrin, PEG-100 Stearate, Phenethyl Alcohol, Phenoxyethanol, Polyester-8, Polyquaternium-51, Quercus Petraea Fruit Extract, Royal Jelly Powder, Royal Jelly, Salix Alba (Willow) Bark Extract, Silica, Sodium Acrylates Crosspolymer-2, Sodium Hyaluronate, Sodium PCA, Styrene/Acrylates Copolymer, Tetrapeptide-45, Theobroma Cacao (Cocoa) Seed Extract, Tocopherol, Trehalose, Triacetin, Urea, Water/Aqua, Xanthan Gum, Yeast Extract


Jafra Royal Men

Royal Jelly

3-in-1 Face Moisturizer Broad Spectrum SPF 20

75 ml 2.5 Fl Oz

143 mm



Drug Facts

Active ingredients	Purpose
Avobenzene 3%.....	Sunscreen
Homosalate 10%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Octocrylene 10%.....	Sunscreen

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Drug Facts (continued)

Directions

- apply liberally 15 minutes before sun exposure
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JAFRA
**ROYAL
MEN**

ROYAL JELLY



3-IN-1 FACE MOISTURIZER
BROAD SPECTRUM SPF 20



75 ml e 2.5 FL OZ (US)

Drug Facts (continued)

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aluminum Starch Octenylsuccinate, Arachidyl Alcohol, Arachidyl Glucoside, Arginine, Behenyl Alcohol, Bisabolol, Butylene Glycol, Butyloctyl Salicylate, Butylphenyl Methylpropional (Lilial), Butyrospermum Parkii (Shea) Butter, C13-16 Isoparaffin, Caffeine, Capryloyl Glycerin/Sebacic Acid Copolymer, Cetyl Alcohol, Citral, Citronellol, Coumarin, Dimethicone, Dipropylene Glycol, Disodium EDTA, Ethylhexyl Methoxycrylene, Ethylhexylglycerin, Fragrance /Parfum, Glycerin, Glyceryl Stearate, Heptyl Undecylenate, Hydrogenated Lecithin, Lauroyl Lysine, Lecithin, Limonene, Linalool, Maltodextrin, PEG-100 Stearate, Phenethyl Alcohol, Phenoxyethanol, Polyester-8, Polyquaternium-51, Quercus Petraea Fruit Extract, Royal Jelly Powder, Royal Jelly, Salix Alba (Willow) Bark Extract, Silica, Sodium Acrylates Crosspolymer-2, Sodium Hyaluronate, Sodium PCA, Styrene/Acrylates Copolymer, Tetrapeptide-45, Theobroma Cacao (Cocoa) Seed Extract, Tocopherol, Trehalose, Triacetin, Urea, Water/Aqua, Xanthan Gum, Yeast Extract

Other information

- protect this product from excessive heat and direct sun

Made in Mexico for:
JAFRA Cosmetics International, Inc.
Westlake Village, CA 91361
Distributed in EU: JAFRA Cosmetics
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Hecho en México para:
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JAFRA y JAFRA Royal Jelly son Marcas
Registradas en México;
Reg US Pat & TM off
LOS ANGELES - ZURICH - MUNICH
MEXICO CIT Y - JAKARTA

3-IN-1 FACE MOISTURIZER BROAD SPECTRUM SPF 20

avobenzene, homosalate, octisalate, octocrylene jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-283
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ROYAL JELLY (UNII: L497I37F0C)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
UREA (UNII: 8W8T17847W)	
DOCOSANOL (UNII: 9G1OE216XY)	
LEVOMENOL (UNII: 24WE03BX2T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SHEA BUTTER (UNII: K49155WL9Y)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
TRIACETIN (UNII: XHX3C3X673)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALLANTOIN, (+)- (UNII: XDK458E1J9)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
C13-16 ISOPARAFFIN (UNII: LED42LZG6O)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
LAUROYL LYSINE (UNII: 113171Q70B)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
CAFFEINE (UNII: 3G6A5W338E)	
CITRAL (UNII: T7EU0O9VPP)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCOA (UNII: D9108TZ9KG)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
HEPTYL UNDECYLENATE (UNII: W77QUB6GXO)
PEG-100 STEARATE (UNII: YD01N1999R)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
COUMARIN (UNII: A4VZ22K1WT)
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)
ARGININE (UNII: 94ZLA3W45F)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
TREHALOSE (UNII: B8WCK70T7I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-283-01	75 mL in 1 CARTON; Type 0: Not a Combination Product	03/27/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/27/2019	

Labeler - Jafra cosmetics International (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture(68828-283)

Revised: 3/2019

Jafra cosmetics International