

JAFRA ROYAL LUNA BRIGHT KIT- avobenzone, homosalate, octisalate, octocrylene

JAFRA COSMETICS INTERNATIONAL INC

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 Royal Luna Bright Kit

Active Ingredient(s)

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 7%

Purpose

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 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 measures including:

- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses

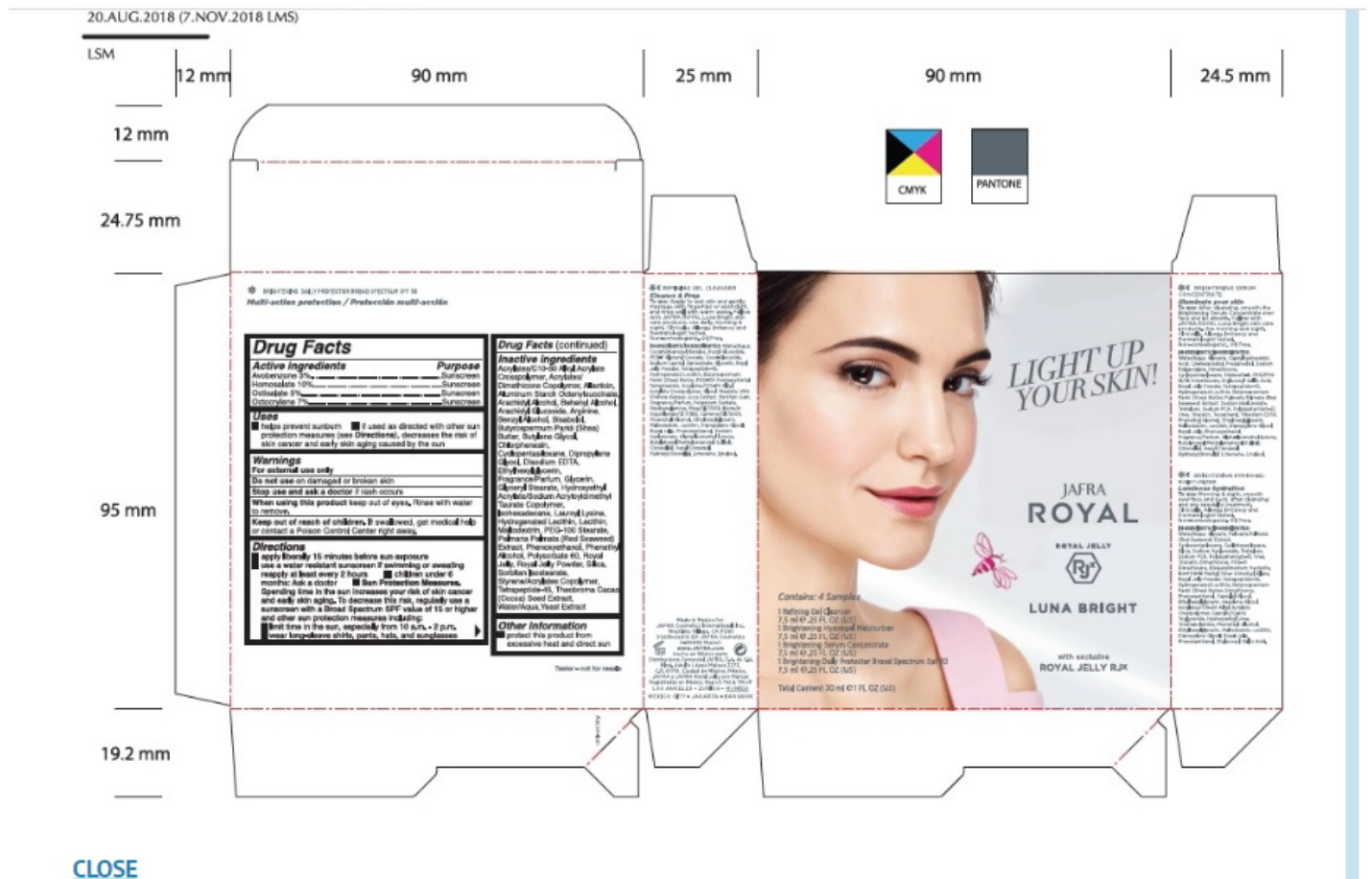
Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/Dimethicone Copolymer, Allantoin, Aluminum Starch Octenylsuccinate, Arachidyl Alcohol, Behenyl Alcohol, Arachidyl Glucoside, Arginine, Benzyl Alcohol, Bisabolol, Butyrospermum Parkii (Shea) Butter, Butylene Glycol, Chlorphenesin, Cyclopentasiloxane, Dipropylene Glycol, Disodium EDTA, Ethylhexylglycerin, Fragrance/Parfum, Glycerin, Glyceryl Stearate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Lauroyl Lysine, Hydrogenated Lecithin, Lecithin, Maltodextrin, PEG-100 Stearate, Palmaria Palmata (red seaweed) Extract, Phenoxyethanol, Phenethyl Alcohol, Polysorbate 60, Royal Jelly, Royal Jelly Powder, Silica, Sorbitan Isostearate, Styrene/Acrylates Copolymer, Tetrapeptide-45, Theobroma Cacao (Cocoa) Seed Extract, Water/Aqua, Yeast Extract

Other information

Protect this product from excessive heat and direct sun

Product label



JAFRA ROYAL LUNA BRIGHT KIT

avobenzone, homosalate, octisalate, octocrylene kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68828-757

Packaging

#

Item Code

Package Description

Marketing Start Date

Marketing End Date

1

NDC:68828-757-01

1 in 1 KIT; Type 1: Convenience Kit of Co-Package

01/12/2022

05/01/2023

Quantity of Parts

Part #

Package Quantity

Total Product Quantity

Part 1

1 TUBE

7.5 mL

Part 2

1 TUBE

7.5 mL

Part 3

1 TUBE

7.5 mL

Part 4

1 TUBE

7.5 mL

Part 1 of 4

REFINING GEL CLEANSER

face and neck (excluding shaving preparations)

Product Information

Other Ingredients

Ingredient Kind

Ingredient Name

Quantity

INGR

WATER (UNII: 059QF0KO0R)

INGR

COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)

INGR

DECYL GLUCOSIDE (UNII: Z17H97EA6Y)

INGR

PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)

INGR

COCO GLUCOSIDE (UNII: ICS790225B)

INGR

SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)

INGR

GLYCERIN (UNII: PDC6A3C0OX)

INGR

ROYAL JELLY (UNII: L497I37F0C)

INGR

HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)

INGR

SHEA BUTTER (UNII: K49155WL9Y)

INGR

PEG-150 PENTAERYTHRITYL TETRASTEARATE (UNII: 8L4OOQ76AM)

INGR

CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)

INGR	GLYCOL STEARATE (UNII: 0324G66D0E)	
INGR	WINE GRAPE JUICE (UNII: JHQ6158A7R)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	MICA (UNII: V8A1AW0880)	
INGR	BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
INGR	PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	MALTODEXTRIN (UNII: 7CVR7L4A2D)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	DIPROPYLENE GLYCOL (UNII: E107L85C40)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
INGR	BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
INGR	.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
INGR	.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
INGR	HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.5 mL in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Part 2 of 4

BRIGHTENING HYDROGEL MOISTURIZER

face and neck (excluding shaving preparations)

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
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INGR	DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	PALMARIA PALMATA (UNII: 7832HOY4ZQ)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	TREHALOSE (UNII: B8WCK70T7I)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	UREA (UNII: 8W8T17847W)	
INGR	TRIACETIN (UNII: XHX3C3X673)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	BIS-PEG-18 METHYL ETHER DIMETHYL SILANE (UNII: OEB4R3WW9C)	
INGR	ROYAL JELLY (UNII: L497I37F0C)	
INGR	HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	HYDROXYETHYL UREA (UNII: MBQ7DDQ7AR)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
INGR	MALTODEXTRIN (UNII: 7CVR7L4A2D)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	DIPROPYLENE GLYCOL (UNII: E107L85C40)	
INGR	CYCLOMETHICONE 6 (UNII: XHK3U310BA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.5 mL in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Part 3 of 4

BRIGHTENING SERUM CONCENTRATE

other skin care preparations

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
INGR	1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
INGR	PROPANEDIOL (UNII: 5965N8W85T)	
INGR	SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	TRIDECETH-6 (UNII: 3T5PCR2H0C)	
INGR	PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
INGR	ROYAL JELLY (UNII: L497I37F0C)	
INGR	HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	PALMARIA PALMATA (UNII: 7832HOY4ZQ)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	TREHALOSE (UNII: B8WCK70T7I)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	UREA (UNII: 8W8T17847W)	
INGR	TRIACETIN (UNII: XHX3C3X673)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	EDETATE TRISODIUM (UNII: 420IP921MB)	
INGR	PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	MALTODEXTRIN (UNII: 7CVR7L4A2D)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	DIPROPYLENE GLYCOL (UNII: E107L85C40)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
INGR	BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
INGR	.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
INGR	.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
INGR	HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		7.5 mL in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Part 4 of 4

LUNA BRIGHT BRIGHTENING DAILY PROTECTOR BROAD SPECTRUM SPF 30

avobenzene, homosalate, octisalate, octocrylene cream

Product Information

Item Code (Source)	NDC:68828-758
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
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
LAUROYL LYSINE (UNII: 113171Q70B)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G1OE216XY)	
ARGININE (UNII: 94ZLA3W45F)	
LEVOMENOL (UNII: 24WE03BX2T)	
SHEA BUTTER (UNII: K49155WL9Y)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALLANTOIN, (+)- (UNII: XDK458E1J9)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
ARACHIDYL GLUCOSIDE (UNII: 6JWV35JOOJ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

ISOHEXADECANE (UNII: 918X1OUF1E)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DULSE (UNII: 7832HOY4ZQ)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ROYAL JELLY (UNII: L497I37F0C)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PEG-20 SORBITAN ISOSTEARATE (UNII: X958PZJ9ON)	
COCOA (UNII: D9108TZ9KG)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-758-01	7.5 mL in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/12/2022	

Labeler - JAFRA COSMETICS INTERNATIONAL INC (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Distribuidora Comercial Jafra, S.A. de C.V.		951612777	manufacture(68828-757, 68828-758)

Revised: 7/2023

JAFRA COSMETICS INTERNATIONAL INC