

COVER ME SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene lotion
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.

Cover Me Sunscreen SPF 30

Active ingredients Purpose

Avobenzone 3%.....Sunscreen
Homosalate 10%.....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 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.

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.

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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/Dimethicone Copolymer, Allantoin, Aluminum Starch Octenylsuccinate, Arachidyl Alcohol, Arachidyl Glucoside, Arginine, Behenyl Alcohol, Benzyl Alcohol, Bisabolol, Butylene Glycol, Butyrospermum Parkii (Shea) Butter, Camellia sinensis Leaf Extract, Chlorphenesin, Cyclopentasiloxane, Dipropylene Glycol, Disodium EDTA, Ethylhexylglycerin, Fragrance/Parfum, Glycerin, Glyceryl Stearate, Hydrogenated Lecithin, Lauroyl Lysine, Lecithin, Maltodextrin, PEG-100 Stearate, PEG-40 Hydrogenated Castor Oil, Phenethyl Alcohol, Phenoxyethanol, Royal Jelly Powder, Royal Jelly, Silica, Styrene/Acrylates Copolymer, Tetrapeptide-45, Trideceth-9, Theobroma Cacao (Cocoa) Seed Extract, Water/Aqua, Zingiber Officinale (Ginger) Root Extract.

Jafra Royal Boost

Cover Me Sunscreen Broad Spectrum SPF 30



COVER ME SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-280
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: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G1OE216XY)	
SHEA BUTTER (UNII: K49155WL9Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LEVOMENOL (UNII: 24WE03BX2T)	
ARGININE (UNII: 94ZLA3W45F)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
ROYAL JELLY (UNII: L497I37F0C)	
TRIDECETH-9 (UNII: X9HD79I514)	
COCOA (UNII: D9108TZ9KG)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAUROYL LYSINE (UNII: 113171Q70B)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
ALLANTOIN (UNII: 344S277G0Z)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GINGER (UNII: C5529G5JPQ)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-280-01	50 mL in 1 TUBE; Type 0: Not a Combination Product	06/12/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/12/2018	

Labeler - Jafra Cosmetics International (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture(68828-280)

Revised: 6/2018

Jafra Cosmetics International