

SUNSCREEN BROAD SPECTRUM SPF 50 JAFRA- avobenzene, homosalate, octisalate, octocrylene, oxybenzone 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.

Sunscreen SPF 50

Active Ingredients Purpose

Avobenzene 3% Sunscreen

Homosalate 10% Sunscreen

Octisalate 5% Sunscreen

Octocrylene 10% Sunscreen

Oxybenzone 5% 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 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 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 ever 2 hours, especially if swimming, sweating, or after toweling

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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/Dimethicone Copolymer, Acrylates/Octylacrylamide Copolymer, Allantoin, Aluminum Starch Octenylsuccinate, Arachidyl Alcohol, Arachidyl Glucoside, Arginine, Behenyl Alcohol, Bisabolol, Chlorphenesin, Cyclopentasiloxane, Disodium EDTA, Ethylhexylglycerin, Fragrance/parfum, Glyceryl Stearate, Lauroyl Lysine, Methylisothiazolinone, Mica, Silica, Panthenol, PEG-100 Stearate, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Water/Aqua.

Drug Facts

Active ingredients

	Purpose
Avobenzone 3%.....	Sunscreen
Homosalate 10%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Octocrylene 10%.....	Sunscreen
Oxybenzone 5%.....	Sunscreen

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- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: Ask a doctor
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 - limit time in the sun, especially from 10 a.m.-2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses

Drug Facts (continued)

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/Dimethicone Copolymer, Acrylates/Octylacrylamide Copolymer, Allantoin, Aluminum Starch Octenylsuccinate, Arachidyl Alcohol, Arachidyl Glucoside, Arginine, Behenyl Alcohol, Bisabolol, Chlorphenesin, Cyclopentasiloxane, Disodium EDTA, Ethylhexylglycerin, Fragrance/Parfum, Glyceryl Stearate, Lauroyl Lysine, Methylisothiazolinone, Mica, Silica, Panthenol, PEG-100 Stearate, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Water/Aqua

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 D-80636 Munich

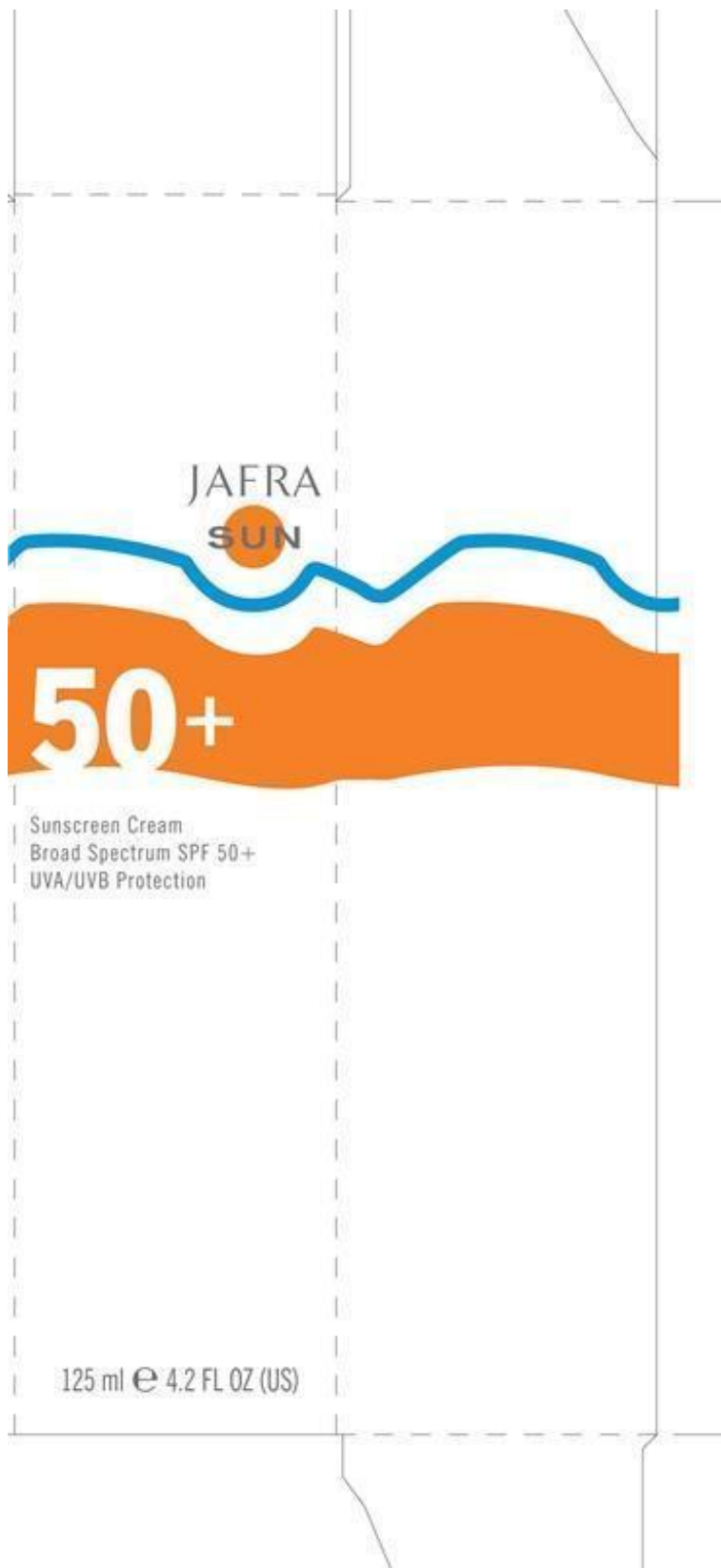


www.JAFRA.com



Hecho en México para:
Distribuidora Comercial JAFRA, S.A. de C.V.
Blvd. Adolfo López Mateos-2273 (antes 515),
C.P. 01049, Distrito Federal, México.
JAFRA es Marca Registrada

LOS ANGELES · ZURICH · MUNICH
MEXICO CITY · MILAN · MOSCOW



Jafra Sun

50+

Sunscreen Cream Broad Spectrum SPF 50+

UVA/UVB Protection

125 ml 4.2 Fl Oz. (US)

SUNSCREEN BROAD SPECTRUM SPF 50 JAFRA

avobenzone, homosalate, octisalate, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-165
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	10 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALLANTOIN (UNII: 344S277G0Z)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35J00J)	
ARGININE (UNII: 94ZLA3W45F)	
DOCOSANOL (UNII: 9G1OE216XY)	
LEVOMENOL (UNII: 24WE03BX2T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LAUROYL LYSINE (UNII: 113171Q70B)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PANTHENOL (UNII: WV9CM0O67Z)	
PEG-100 STEARATE (UNII: YD01N1999R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-165-02	1 in 1 CARTON	02/19/2013	
1	NDC:68828-165-01	125 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68828-165-04	1 in 1 CARTON	02/19/2013	
2	NDC:68828-165-03	200 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 not final	part352	02/19/2013	

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(68828-165)

Revised: 12/2018

JAFRA COSMETICS INTERNATIONAL