

**GOLDEN TAN ALWAYS STAY-ON MAKEUP BROAD SPECTRUM SPF 15 JAFRA-
octinoxate, oxybenzone, titanium dioxide liquid
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.

Golden Tan Always Stay-on Makeup SPF 15

Active Ingredients Purpose

Octinoxate 5% Sunscreen

Oxybenzone 2% Sunscreen

Titanium Dioxide 2.1% 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 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;

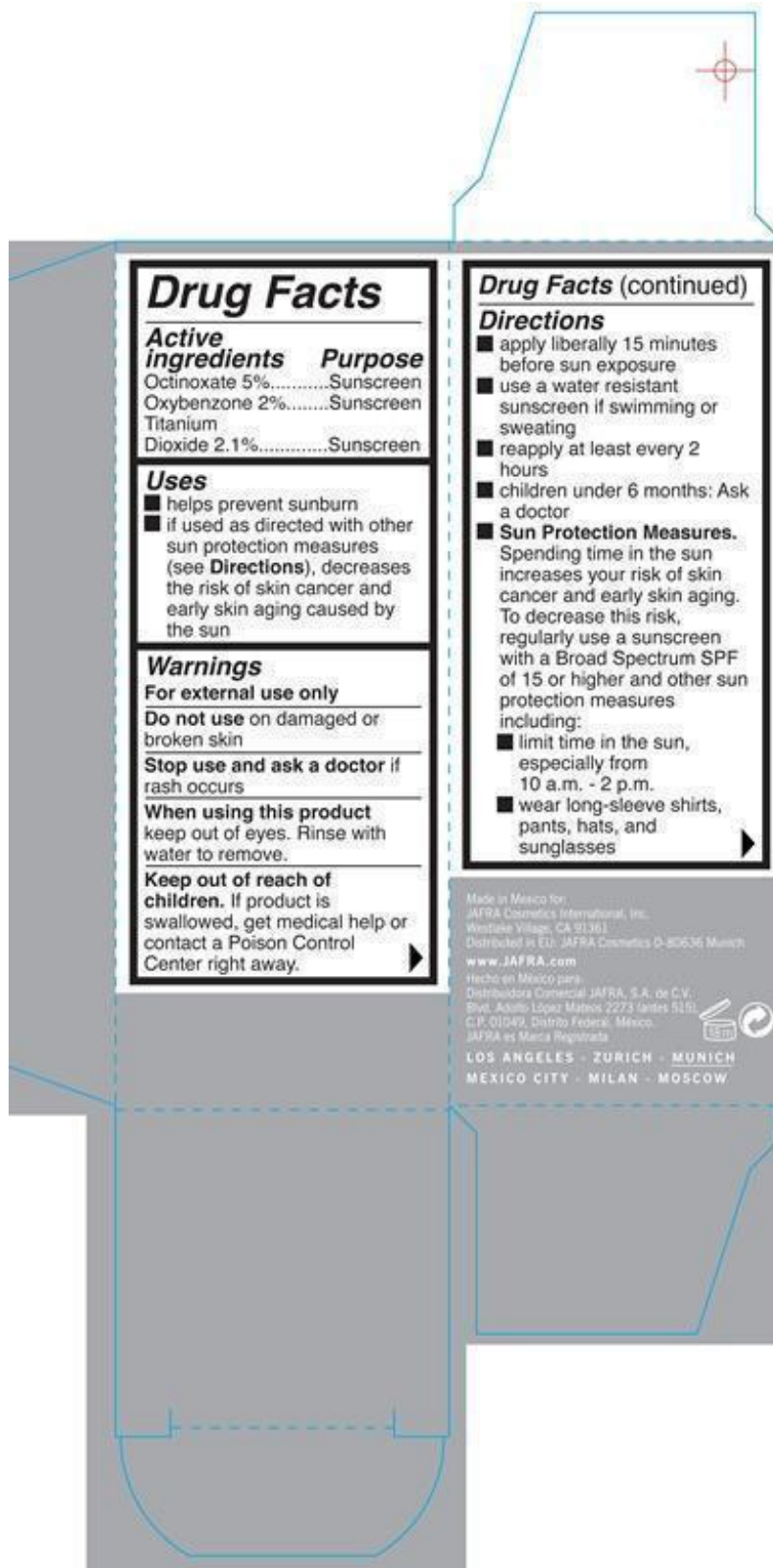
limit time in the sun, especially from 10 a.m. - 2 p.m.

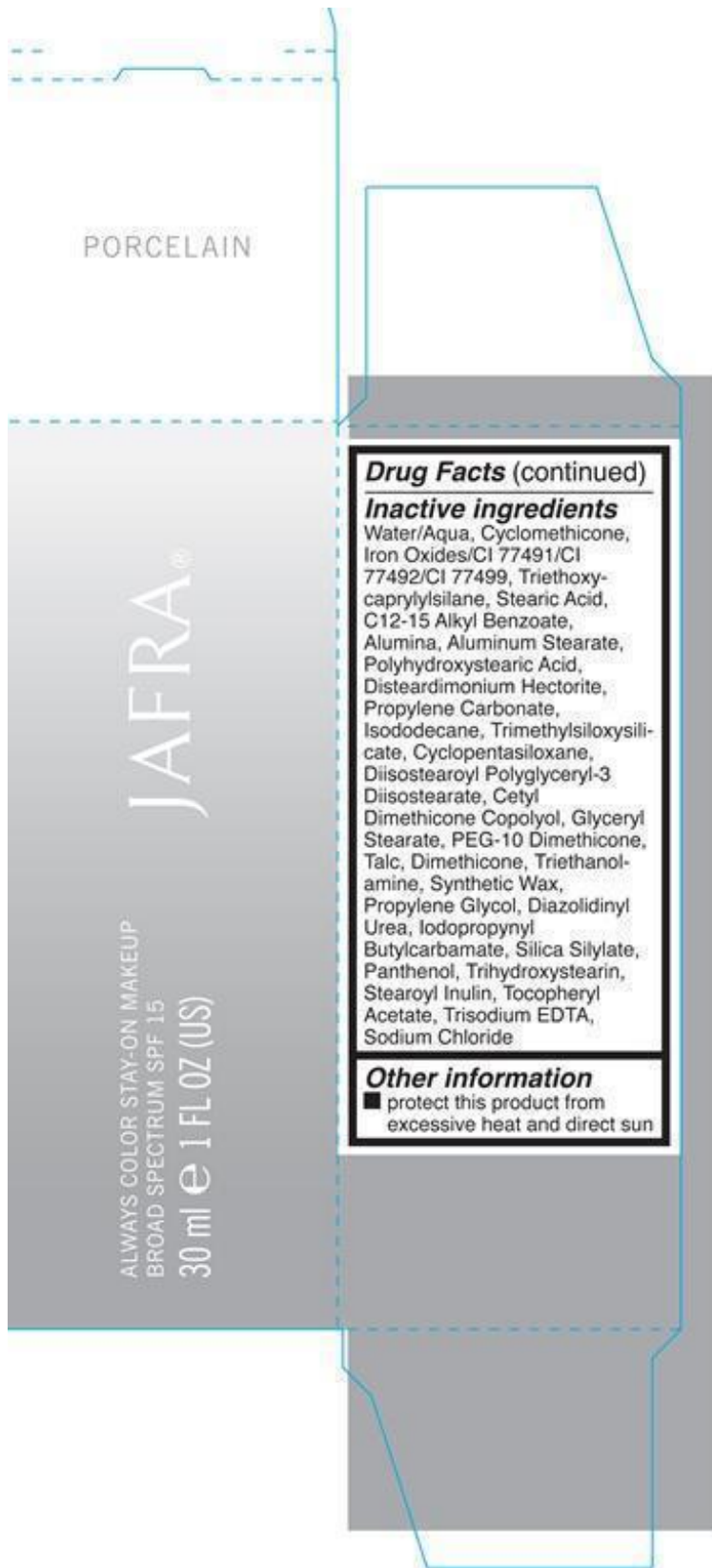
wear long-sleeve shirts, pants, hats, and sunglasses

Inactive ingredients

Water/Aqua, Cyclomethicone, Iron Oxides/CI 77491/77492/77499, Triethoxycaprylsilane, Stearic Acid, C12-15 Alkyl Benzoate, Alumina, Aluminum Stearate, Polyhydroxystearic Acid, Distearidmonium Hectorite, Propylene Carbonate, Isododecane, Trimethylsiloxysilicate, cyclopentasiloxane, Diisostearyl Polyglyceryl-3 Diisostearate, Cetyl Dimethicone Colpolyol, Glyceryl Stearate, PEG-10 Dimethicone, Talc, Dimethicone, Triethanolamine, Synthetic Wax, Propylene Glycol, Diazolidnyl Urea,

Iodopropynyl Butylcarbamate, Silica Silylate, Panthenol, Trihydroxystearin, Stearoyl Inulin, Tocopheryl Acetate, Trisodium EDTA, Sodium Chloride.





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Golden Tan Always Color Stay-on Makeup

Broad Spectrum SPF 15

30 ml 1 Fl Oz

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octinoxate, oxybenzone, titanium dioxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-064
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALUMINUM OXIDE (UNII: LM26O6933)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
ISODODECANE (UNII: A8289P68Y2)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TROLAMINE (UNII: 9O3K93S3TK)	
SYNTHETIC WAX (1800 MW) (UNII: 248P1AUJ90)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)	
PANTHENOL (UNII: WV9CM0O67Z)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-064-02	1 in 1 CARTON	02/27/2013	
1	NDC:68828-064-01	30 mL in 1 BOTTLE, GLASS; 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	02/27/2013	

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(68828-064)

Revised: 1/2019

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