

ALWAYS FOUNDATION MAKEUP BROAD SPECTRUM SPF 15 SOFT IVORY- octinoxate, zinc oxide 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.

Always Foundation Makeup Broad Spectrum SPF 15 Soft Ivory

Active Ingredients Purpose

Octinoxate 3% Sunscreen

Zinc Oxide 6.8% 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.

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
- Children under 6 months of age: ask a doctor.

Inactive ingredients

C12-15 Alkyl Benzoate, Caprylyl Glycol, Caprylyl Methicone, Dimethicone, Dimethicone Crosspolymer, Ethylhexylglycerin, Glycerin, Hexylene Glycol, Hydroxypropylcocoate PEG-8 Dimethicone, Iron Oxides/CI 77491/CI 77492/CI 77499, Kaolin, Lecithin, Methicone, Phenoxyethanol, Phenyl Trimethicone, Propylene carbonate, Silica, Silica Dimethyl Silylate, Sodium Chloride, Stoddard solvent, Titanium Dioxide/CI 77891, Triethoxycaprylsilane, Water/Aqua

Jafra beauty

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Foundation Makeup Broad Spectrum SPF 15 Soft Ivory

30 ml 1 FL OZ (US)

COLR-599

FINAL ART

JAFRA

ONLY USA

UNIT CARTON - JAFRA BEAUTY ALWAYS
FOUNDATION MAKEUP SPF 15
19.JUN.2020

FORMULA: JMB1029-1043
LSM

JMB1033 10004952 Soft Ivory
JMB1034 10004953 Natural Tan
JMB1035 10004954 Golden Tan
JMB1036 10004976 Cocoa
JMB1037 10004977 Shell
JMB1038 10004978 Buff
JMB1039 10004979 Natural
JMB1040 10004990 Ivory
JMB1041 10004991 Bisque
JMB1042 10004992 Honey

+	NATURAL LG14	+	BISQUE MDN4
+	SOFT IVORY LP16	+	BUFF MDP6
+	IVORY LN18	+	HONEY DG18
+	NATURAL TAN MG16	+	COCOA DN20
+	SHELL MP18		
+	GOLDEN TAN MG20		

12 mm

36 mm

36 mm

36 mm

5.45 mm

14 mm



BLACK

match colors according to the approved samples

35.75 mm

SHADE NAME

placement shade name listed

105 mm

Drug Facts

Active ingredients Purpose
Octinoxate 3%.....Sunscreen
Zinc Oxide 6.8%.....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 product is swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

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 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

Drug Facts (continued)

Inactive ingredients

C12-15 Alkyl Benzoate, Caprylyl Glycol, Caprylyl Methicone, Dimethicone, Dimethicone Crosspolymer, Ethylhexylglycerin, Glycerin, Hexylene Glycol, Hydroxypropylcocoate PEG-8 Dimethicone, Iron Oxides/Ci 77491/Ci 77492/Ci 77499, Kaolin, Lecithin, Methicone, Phenoxyethanol, Phenyl Trimethicone, Propylene carbonate, Silica, Silica Dimethyl Silylate, Sodium Chloride, Stoddard solvent, Titanium Dioxide/Ci 77891, Triethoxycaprylsilane, Water/Aqua

Other information

■ protect this product from excessive heat and direct sun

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FOUNDATION
MAKEUP
BROAD SPECTRUM
SPF 15

30 ml e 1 FL OZ (US)

35.75 mm

13 mm

ALWAYS FOUNDATION MAKEUP BROAD SPECTRUM SPF 15 SOFT IVORY

octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-413
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6.8 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
METHICONE (20 CST) (UNII: 6777U11MKT)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSPOG0W)	
WHITE SPIRIT TYPE 1 (UNII: 37LNI1I16R)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
KAOLIN (UNII: 24H4NWX5CO)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
WATER (UNII: 059QF0K00R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE CROSSPOLYMER (45000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-413-01	30 mL in 1 CARTON; Type 0: Not a Combination Product	07/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/14/2020	

Labeler - Jafra Cosmetics International (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture(68828-413)

Revised: 7/2020

Jafra Cosmetics International