ALWAYS FOUNDATION MAKEUP BROAD SPECTRUM SPF 15 SOFT IVORY- homosalate, octis alate, 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

Homosalate 4.25% Purpose Sunscreen

Octisalate 4.75% Purpose Sunscreen

Zinc Oxide 7.0% 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

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

Stop use and ask a doctor if rash occurs

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 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

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, Triethoxycaprylysilane, Water/Aqua

Protect this product from excessive heat and direct sun

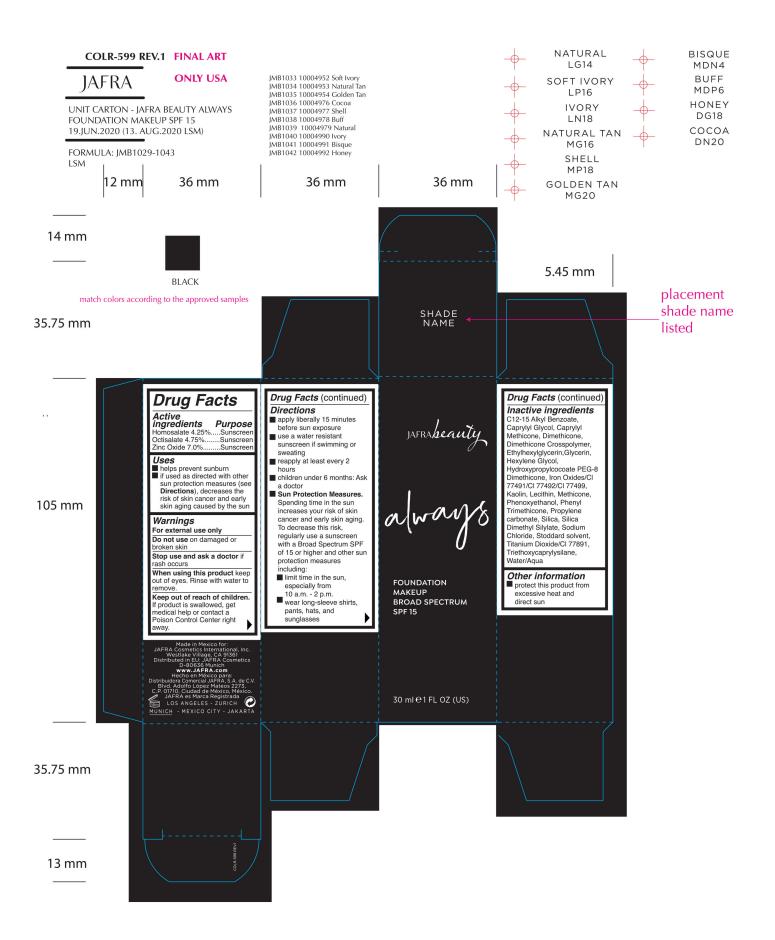
JAFRA beauty

Always

Foundation Makeup

Broad Spectrum SPF 15

30 ML e 1 FL OZ (US)



homosalate, octisalate, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-423
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7 g in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4.25 g in 100 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	4.75 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
DIMETHICO NE (UNII: 92RU3N3Y1O)			
GLYCERIN (UNII: PDC6A3C0OX)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
KAOLIN (UNII: 24H4NWX5CO)			
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)			
WATER (UNII: 059QF0KO0R)			
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)			
CAPRYLYL TRISILO XANE (UNII: Q95M2P1KJL)			
METHICONE (20 CST) (UNII: 6777U11MKT)			
PHENYL TRIMETHICO NE (UNII: DR0 K5NO J4R)			
DIMETHICO NE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLO PENTASILO XANE) (UNII: UF7620L1W6)			
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)			
WHITE SPIRIT TYPE 1 (UNII: 37LNJ1I16R)			
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)			
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
PHENO XYETHANOL (UNII: HIE492ZZ3T)			
PROPYLENE CARBONATE (UNII: 8 D0 8 K3S51E)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:68828-423-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	08/20/2020	
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Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	08/20/2020		

Labeler - JAFRA COSMETICS INTERNATIONAL (041676479)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture(68828-423)	

Revised: 8/2020 JAFRA COSMETICS INTERNATIONAL