ALWAYS FOUNDATION MAKEUP BROAD SPECTRUM SPF 15 BUFF- 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 Buff

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

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.

- 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

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

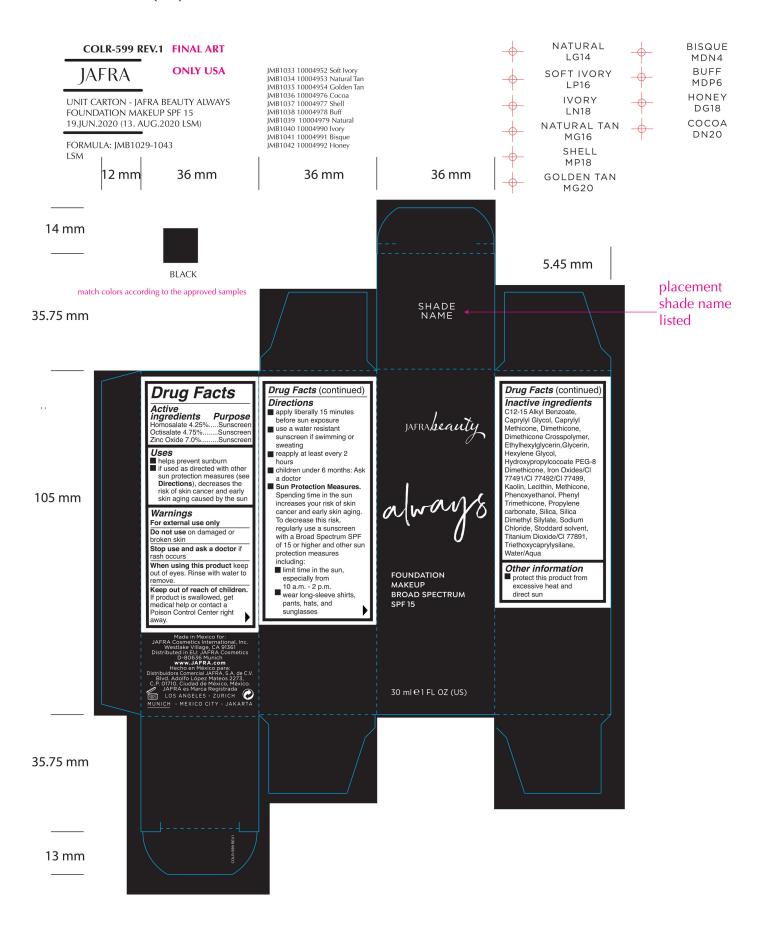
Protect this product from excessive heat and direct sun

JAFRA beauty

Always

Foundation Makeup

Broad Spectrum SPF 15



ALWAYS FOUNDATION MAKEUP BROAD SPECTRUM SPF 15 BUFF

homosalate, octisalate, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-429
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
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
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
METHICONE (20 CST) (UNII: 6777U11MKT)	
WATER (UNII: 059QF0KO0R)	
DIMETHICO NE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLO PENTASILO XANE) (UNII: UF7620L1W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE CARBONATE (UNII: 8 D0 8 K3 S51E)	
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
WHITE SPIRIT TYPE 1 (UNII: 37LNJ1116R)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
KAOLIN (UNII: 24H4NWX5CO)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
CAPRYLYL TRISILO XANE (UNII: Q95M2P1KJL)	
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)	
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NOJ4R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

# Item Code Package Description Marketing Start Date Marketing	
	End Date
1 NDC:68828-429-01 30 mL in 1 TUBE; Type 0: Not a Combination Product 08/21/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	08/21/2020		

Labeler - JAFRA COSMETICS INTERNATIONAL (041676479)

Establishment			
Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture(68828-429)

Revised: 8/2020 JAFRA COSMETICS INTERNATIONAL