

ALWAYS FOUNDATION MAKEUP BROAD SPECTRUM SPF 15 HONEY- homosalate, octisalate, 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 Honey

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, Triethoxycaprylsilane, 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)

COLR-599 REV.1 FINAL ART

JAFRA

ONLY USA

UNIT CARTON - JAFRA BEAUTY ALWAYS
FOUNDATION MAKEUP SPF 15
19.JUN.2020 (13. AUG.2020 LSM)

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

SOFT IVORY
LP16

IVORY
LN18

NATURAL TAN
MG16

SHELL
MP18

GOLDEN TAN
MG20

BISQUE
MDN4
BUFF
MDP6
HONEY
DG18
COCOA
DN20

12 mm

36 mm

36 mm

36 mm

14 mm



BLACK

match colors according to the approved samples

35.75 mm

5.45 mm

SHADE
NAME

placement
shade name
listed

105 mm

Drug Facts

Active Ingredients Purpose
Homosalate 4.25%.....Sunscreen
Octisalate 4.75%.....Sunscreen
Zinc Oxide 7.0%.....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

JAFRA beauty

always

FOUNDATION
MAKEUP
BROAD SPECTRUM
SPF 15

30 ml e 1 FL OZ (US)

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,
C.P. 01710, Ciudad de México, México.
JAFRA es Marca Registrada
LOS ANGELES - ZURICH
MUNICH - MEXICO CITY - JAKARTA

35.75 mm

13 mm

ALWAYS FOUNDATION MAKEUP BROAD SPECTRUM SPF 15 HONEY

homosalate, octisalate, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-430
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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	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
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
WATER (UNII: 059QF0KO0R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)	
WHITE SPIRIT TYPE 1 (UNII: 37L呢J1116R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE CROSSPOLYMER (450000 MPa.s AT 12 % IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
KAOLIN (UNII: 24H4NWX5CO)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-430-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	08/20/2020	

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(68828-430)

Revised: 8/2020

JAFRA COSMETICS INTERNATIONAL