

**HYDRATION DYNAMICS MOISTURE REPLENISHMENT SPF 15- octinoxate octisalate
oxybenzone 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.

HYDRATION DYNAMICS MOISTURE REPLENISHMENT CREAM SPF-15

SUNSCREEN ACTIVE INGREDIENT (SPF 15):

OCTINOXATE/ETHYLHEXYL METHOXYCINNAMATE, OCTISALATE/ETHYLHEXYL SALICYLATE, OXYBENZONE/BENZOPHENONE-3

PURPOSE: SUNSCREEN

OTHER INGREDIENTS: WATER/AQUA, CAPRYLIC/CAPRIC TRIGLYCERIDE, DIMETHICONE, PEG-8 BEESWAX/CERA ALBA, POLYACRYLAMIDE, C13-14 ISOPARAFFIN, LAURETH-7, CETYL ALCOHOL, CETETH-20, STEARETH-20, GLYCERIN, METHYLSILANOL MANNURONATE, HEMIDESMUS INDICUS EXTRACT, GLYCYRRHIZA GLABRA (LICORICE) EXTRACT, WITHANIA SOMNIFERIA EXTRACT, BUTYLENE GLYCOL, SACCHARIDE ISOMERATE, SODIUM PCA, SODIUM HYALURONATE, TREHALOSE, POLYQUATERNIUM-51, UREA, GLYCERYL STEARATE, HYDROGENATED AVOCADO OIL, DIMETHICONE, DIMETHICONE CROSSPOLYMER, BUTYROSPERMUM PARKII (SHEA BUTTER) FRUIT, PROPYLENE GLYCOL, CODIUM TOMENTOSUM EXTRACT, DIAZOLIDINYL UREA, IODOPROPYNYL BUTYLCARBAMATE, FRAGRANCE/PARFUM, ACRYLATES COPOLYMER, CHONDRUS CRISPUS (CARRAGEENAN) EXTRACT, BIOSACCHARIDE GUM-4, PANTHENOL, TOCOPHERYL ACETATE, TRISODIUM EDTA, GLYCINE SOYA (SOYBEAN) SEED EXTRACT, CERAMIDE 3, GLYCERYL POLYMETHACRYLATE, PALMITOYL OLIGOPEPTIDE, PENTYLENE GLYCOL, PROPAMIDOBENZOIC ACID, ZINGIBER OFFICINALE (GINGER) EXTRACT, BISABOLOL, RED 33/CI 17200, BLUE 1/CI 42090 [FRAGRANCE/PARFUM CONTAINS: CINNAMYL ALCOHOL, HYDROXYCITRONELLAL, BENZYL SALICYLATE, HYDROXYISOHEXYL 3-CYCLOHEXANE CARBOXALDEHYDE (LYRAL), BENZYL BENZOATE, CITRONELLOL, ALPHA-ISOMETHYL IONONE]

MOISTURE REPLENISHING CREAM SPF 15

TO USE: IN THE MORNING AFTER CLEANSING, SMOOTH OVER FACE AND THROAT.

DISCONTINUE USE IF IRRITATION OCCURS.

KEEP OUT OF REACH OF CHILDREN.

JAFRA

HYDRATION DYNAMICS

MOISTURE REPLENISHING CREAM SPF 15



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HYDRATION DYNAMICS



MOISTURE REPLENISHING CREAM SPF 15

CREMA FACIAL ULTRAHIDRATANTE CON FPS 15

WITH / CON INTELLISHIELD

50 ml e 1.7 FL OZ (US)

SUNSCREEN ACTIVE INGREDIENTS (SPF 15): Octinoxate/Ethylhexyl Methoxycinnamate, Octisalate/Ethylhexyl Salicylate, Oxybenzone/Benzophenone-3. **OTHER INGREDIENTS:** Water/Aqua, Caprylic/Capric Triglyceride, Dimethicone, PEG-8 Beeswax/Cera Alba, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Cetyl Alcohol, Ceteth-20, Steareth-20, Glycerin, Methylsilanol Mannuronate, Hemidesmus Indicus Extract, Glycyrrhiza Glabra (Licorice) Extract, Withania Somnifera Extract, Butylene Glycol, Saccharide Isomerate, Sodium PCA, Sodium Hyaluronate, Trehalose, Polyquaternium-51, Urea, Glyceryl Stearate, Hydrogenated Avocado Oil, Dimethicone, Dimethicone Crosspolymer, Butyrospermum Parkii (Shea Butter) Fruit, Propylene Glycol, Codium Tomentosum Extract, Diazolidinyl Urea, Iodopropinyl Butylcarbamate, Fragrance/Parfum, Acrylates Copolymer, Chondrus Crispus (Carrageenan) Extract, Biosaccharide Gum-4, Panthenol, Tocopheryl Acetate, Trisodium EDTA, Glycine Soja (Soybean) Seed Extract, Ceramide 3, Glyceryl Polymethacrylate, Palmitoyl Oligopeptide, Pentylene Glycol, Propamidobenzoic Acid, Zingiber Officinale (Ginger) Extract, Bisabolol, Red 33/CI 17200, Blue 1/CI 42090 [Fragrance/Parfum contains; Cinnamyl Alcohol, Hydroxycitronellal, Benzyl Salicylate, Hydroxyisohexyl 3-Cyclohexane Carboxaldehyde (Lyral), Benzyl Benzoate, Citronellol, Alpha-Isomethyl Ionone]

INGREDIENTES: Agua, Metoxicinamato de Octilo, Triglicérido Caprílico/Cáprico, Salicilato de Octilo, Dimeticona, PEG-8 Cera de Abeja, Isomerato de Sacáridos, Estearato de Glicerilo, Poli(ac)rilamida, Isoparafina C13-14, Lauret-7, Benzofenona-3, Alcohol Cetílico, Cetet-20, Estearat-20, Glicerina, Manuronato de Metilsilanol, Extracto de Hemidesmus Indicus, Extracto de Regaliz (Glycyrrhiza glabra), Extracto de Withania Somnifera, Butilenglicol, PCA Sódico, Hialuronato de Sodio, Trehalosa, Policuaternio-51, Urea, Aceite de Aguacate Hidrogenado, Dimeticona, Cropolímero de Dimeticona, Manteca de Karité (Butyrospermum parkii), Propilenglicol, Extracto de Codium tomentosum, Diazolidinil urea, Yodopropinil Butilcarbamato, Copolímero de Acrilatos, Extracto de carragenina (Chondrus crispus), Biosacárido Goma-4, Fragancia, Pantenol, Acetato de Tocoferilo, EDTA Trisódico, Extracto de Semilla de Soya (Glycine soja), Ceramida 3, Polimetacrilato de Glicerilo, Palmitoil Oligopéptido, Rojo No.33, Azul No.1, Pentilén Glicol, Ácido Propamidobenzoico, Extracto de Jengibre (Zingiber officinale), Bisabolol, [Fragancia contiene: Alcohol cinámico, Hidroxicitronelal, Salicilato bencilico, Hidroximetil-pentiliciclohexenocarbaldehído, Benzoato de bencilo, Citronelol, 3-metil-4-(2,6,6-trimetil-2-ciclohexen-1-il)buten-2-ona]

Contains: Oxybenzone / Enthält: Oxybenzon / Contiene: Oxybenzone.

HYDRATION DYNAMICS



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**MOISTURE REPLENISHING
CREAM SPF 15**

JAFRA CREMA FACIAL ULTRAHIDRATANTE
CON FPS 15

WITH INTELLISHIELD

Feuchtigkeit aufbauende Tagescreme SPF 15
Crema Idratante Restitutiva da Giorno SPF15

To use: In the morning after cleansing, smooth over face and throat.
Clinically, allergy, irritancy and dermatologist tested.

Instrucciones de Uso: Utilizar por la mañana después de la limpieza, aplicar suavemente sobre rostro y cuello. Clínica y dermatológicamente probada en alergia e irritación.

FPS=Factor de Protección Solar

50 ml e 1.7 FL OZ (US)

MOISTURE REPLENISHING CREAM SPF 15 / CREMA FACIAL ULTRAHIDRATANTE CON FPS 15
FEUCHTIGKEITSAUFBAUENDE TAGESCREME SPF 15 / CREMA IDRATANTE DA GIORNO SPF15 PER PELLI SENSIBILI



For dry skin, Para condiciones de piel seca, Für Haut mit niedrigem Feuchtigkeitsgehalt, Per pelli con basso livello di idratazione.
To use: In the morning after cleansing, smooth over face and throat. Clinically, allergy, irritancy and dermatologist tested. Discontinue use if irritation occurs. Keep out of reach of children.
Instrucciones de uso: Utilizar por la mañana después de la limpieza, aplicar suavemente sobre rostro y cuello. Clínica y dermatológicamente probada en alergia e irritación. Suspender su uso en caso de irritación. No se deje al alcance de los niños. **FPS=Factor de Protección Solar.**
Anwendung: Täglich morgens nach Reinigung und Gesichtswasser auf Gesicht und Hals auftragen. Auf Allergien und Irritationen klinisch und dermatologisch getestet. Anwendung abbrechen, wenn Irritationen auftreten, Von Kindern fernhalten.
Uso: ogni mattino, dopo Detergente e Tónico, applicare su viso e collo. Clinicamente testato contro allergia e irritazione. Interrompere l'uso in caso d'irritazione. Tenere lontano dalla portata dei bambini.

Contains: Oxybenzone / Contiene: Oxybenzone / Enthält: Oxybenzon
 Contains INTELLISHIELD, a technological masterpiece that acts like an invisible film that mimics real skin.
 Contiene INTELLISHIELD, un avance tecnológico que actúa como una segunda piel ó como una película invisible que se mimetiza con la piel para protegerla.
 Beinhaltet INTELLISHIELD, ein technologisches Kunstwerk, das der Haut und ihren natürlichen Funktionen nachempfunden ist und wie eine zweite, unsichtbare Haut schützt.
 Contiene INTELLISHIELD, uno speciale complesso ad alta tecnologia che agisce come una pellicola invisibile, imitando la vera pelle.
SUNSCREEN ACTIVE INGREDIENTS (SPF 15): Octinoxate/Ethylhexyl Methoxycinnamate, Octisalate/Ethylhexyl Salicylate, Oxybenzone/Benzophenone-3
OTHER INGREDIENTS: Water/Aqua, Caprylic/Capric Triglyceride, Dimethicone, PEG-8 Beeswax/Cera Alba, Saccharide Isomerate, Glyceryl Stearate, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Cetyl Alcohol, Ceteth-20, Steareth-20, Glycerin, Methylsilanol Mannuronate, Hemidesmus Indicus Extract, Glycyrrhiza Glabra (Licorice) Extract, Withania Somnifera Extract, Butylene Glycol, Sodium PCA, Sodium Hyaluronate, Trehalose, Polyquaternium-51,Urea, Hydrogenated Avocado Oil, Dimethicone, Dimethicone Crosspolymer, Butyrospermum Parkii (Shea Butter) Fruit, Propylene Glycol, Codium Tomentosum Extract, Diazolidinyl Urea, Yodopropinyl Butylcarbamate, Acrylates Copolymer, Chondrus Crispus (Carrageenan) Extract, Biosaccharide Gum-4, Fragrance/Parfum, Panthenol, Tocopheryl Acetate, Trisodium EDTA, Glycine Soja (Soybean) Seed Extract, Ceramide 3, Glyceryl Polymethacrylate, Palmitoyl Oligopeptide, Red 33/CI 17200, Blue 1/CI 42090, Pentylene Glycol, Propamidobenzoic Acid, Zingiber Officinale (Ginger) Extract, Bisabolol (Fragrance/Parfum contains: Cinnamyl Alcohol, Hydroxycitronellal, Benzyl Salicylate, Hydroxyisohexyl 3-Cyclohexane Carboxaldehyde (Lyral), Benzyl Benzoate, Citronellol, Alpha-Isomethyl Ionone).
INGREDIENTES: Agua, Metoxicinamato de Octilo, Triglicérido Caprílico/Cáprico, Salicilato de Octilo, Dimeticona, PEG-8 Cera de Abeja, Isomero de Sacáridos , Estearato de Glicerilo, Poliacrilamida, Isoparafina C13-14, Lauret-7, Benzofenona-3, Alcohol Cetílico, Cetel-20, Estereol-20, Glicerina, Manuronato de Metilsilanol, Extracto de Hemidesmus Indicus, Extracto de Regaliz (Glycyrrhiza glabra), Extracto de Withania Somnifera, Butilenglicol, PCA Sódico, Hialuronato de Sodio, Trehalosa, Policuaternio-51, Urea, Aceite de Aguacate Hidrogenado, Cospolímero de Dimeticona, Manteca de Karité (Butyrospermum parkii), Propilenglicol, Extracto de Codium tomentosum, Diazolidinil urea, Yodopropinil Butilcarbamato, Copolímero de Acrilatos, Extracto de carragenina (Chondrus crispus), Biosacárido Goma-4, Fragancia, Pantenol, Acetato de Tocoferilo, EDTA Trisódico, Extracto de Semilla de Soja (Glycine soja), Ceramida 3, Polimetacrilato de Glicerilo, Palmitolil Oligopéptido, Rojo No.33, Azul No.1, Pentileno Glicol, Ácido propamidobenzóico, Extracto de Jengibre (Zingiber officinale), Bisabolol (Fragancia contiene: Alcohol cinámico, Hidroxicitronelil, Salicilato de Bencilo, Hidroximetil-pentiliciclohexenocarbaldehído, Benzoato de bencilo, Citronelil, 3-metil-4-(2,6,6-trimetil-2-ciclohexen-1-il)-3-buten-2-ona),

HYDRATING TONER / LOCIÓN FACIAL FRESCANTE HIDRATANTE / FEUCHTIGKEITSSPENDENDES GESICHTSWASSER / TONICO IDRATANTE



To use: Use morning and night after cleansing. Sweep on with a cotton pad over face and throat. Follow with treatment and/or moisturizer. Clinically, allergy, irritancy and dermatologist tested.
Instrucciones de Uso: Utilice por la mañana y por la noche. Con ayuda de un algodón, aplique sobre rostro y cuello. Posteriormente aplique la humectante JAFRA que utiliza regularmente. Clínica y dermatológicamente probada en alergia e irritación.
Anwendung: Täglich morgens und abends nach der Gesichtereinigung ein Wattepad mit dem Gesichtswasser anfeuchten und behutsam auf Gesicht und Hals anwenden. Mit Tages- bzw. Nachtpflege folgen. Auf Allergien und Irritationen klinisch und dermatologisch getestet.
Uso: ogni giorno mattina e sera, dopo il Detergente, applicare su una spugnetta o un panno di cotone e massaggiare su viso e collo; seguire con prodotti specifici e/o l'idratante. Clinicamente testato contro allergia e irritazione.

INGREDIENTS: Water/Aqua, Sodium PCA, Glyceryl Polymethacrylate, Propylene Glycol, PVM/MA Copolymer, Rosa Centifolia Flower Water, Glycerin, Polysorbate 20, Hemidesmus Indicus Extract, Glycyrrhiza Glabra (Licorice) Extract, Withania Somnifera Extract, Butylene Glycol, Diazolidinyl Urea, Yodopropinyl Butylcarbamate, Panthenol, Alantoin, Trisodium EDTA, Sodium Hyaluronate, Trehalose, Polyquaternium-51, Urea, Methylsilanol Mannuronate, Pentylene Glycol, Propamidobenzoic Acid, Fragrance/Parfum, Menthone Glycerin Acetate, Citric Acid, Red 33/CI 17200, Blue 1/CI 42090 (Fragrance/Parfum contains: Cinnamyl Alcohol, Hydroxycitronellal, Benzyl Salicylate, Hydroxyisohexyl 3-Cyclohexane Carboxaldehyde (Lyral), Benzyl Benzoate, Citronellol, Alpha-Isomethyl Ionone).
INGREDIENTES: Agua, PCA Sódico, Polimetacrilato de Glicerilo, Propilenglicol, Copolímero PVM/MA, Agua de Flor de Rosa (Rosa centifolia), Glicerina, Polisorbato 20, Extracto de Hemidesmus Indicus, Extracto de Regaliz (Glycyrrhiza glabra), Extracto de Withania Somnifera, Butilenglicol, Diazolidinil urea, Yodopropinil Butilcarbamato, Pantenol, Alantoina, EDTA Trisódico, Hialuronato de Sodio, Trehalosa, Policuaternio-51, Urea, Manuronato de Metilsilanol, Pentileno Glicol, Ácido Propamidobenzóico, Fragancia, Mentona Glicerina Acetato, Ácido Cítrico, Rojo No.33, Azul No.1 (Fragancia contiene: Alcohol cinámico, Hidroxicitronelil, Salicilato de Bencilo, Hidroximetil-pentiliciclohexenocarbaldehído, Benzoato de bencilo, Citronelil, 3-metil-4-(2,6,6-trimetil-2-ciclohexen-1-il)-3-buten-2-ona),

JAFRA
 HYDRATION DYNAMICS
 MOISTURE REPLENISHING CREAM SPF 15
 CREMA FACIAL ULTRAHIDRATANTE CON FPS 15
 WITH INTELLISHIELD
 7,5 ml e
 7.5 ml .25 FL OZ (US)

Feuchtigkeit aufbauende Tagescreme SPF 15
Crema Idratante da Giorno SPF15 per Pelli Sensibili
 FPS=Factor de Protección Solar.
JAFRA
 Founded by Jan and Frank Day SINCE 1956
 Made in Mexico for:
 Jafra Cosmetics International, Inc.
 Westlake Village, CA 91361
www.JAFRA.com
 Hecho en México para: Distribuidora Comercial Jafra, S.A. de C.V.
 Blvd. Adolfo López Mateos 515, Col. Tlacopac, México D. F., 01040
 Jafra es Marca Registrada
LOS ANGELES - ZURICH MUNICH - MEXICO CITY MILAN

HYDRATION DYNAMICS MOISTURE REPLENISHMENT SPF 15			
octinoxate octisalate oxybenzone cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-156
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
LAURETH-7 (UNII: Z95S6G8201)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETETH-20 (UNII: I835H2IHHX)	
STEARETH-20 (UNII: L0Q8IK9E08)	
HEMIDESMUS INDICUS ROOT (UNII: Y5CFT48S90)	
BIO SACCHARIDE GUM-1 (UNII: BB4PU4V09H)	
PHYLLANTHUS EMBLICA FRUIT (UNII: YLX4CW2576)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
SHEA BUTTER (UNII: K49155WL9Y)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HYDROXYPHENYL PRO PAMIDO BENZOIC ACID (UNII: 25KRT26H77)	
PEG-4 LAURATE (UNII: AYP4VM3N1Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLSILANOL ASCORBATE (UNII: 46Z5D1I0IS)	
WITHANIA SOMNIFERA FLOWER (UNII: 2HZ95R7082)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TREHALOSE (UNII: B8WCK70T7I)	
POLIDRONIUM CHLORIDE (UNII: 6716Z5YR3G)	
UREA (UNII: 8W8T17847W)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CODIUM TOMENTOSUM (UNII: B8B45BRU87)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
SOYBEAN SEED OIL (UNII: P6C7NVO1UF)	
CERAMIDE 3 (UNII: 4370DF050B)	

GLYCERYL 1-ADIPATE (UNII: 6UXO8KCR3J)	
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
GINGER (UNII: C5529G5JPQ)	
LEVOMENOL (UNII: 24WE03BX2T)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-156-12	1 in 1 BOX		
1	NDC:68828-156-62	50 mL in 1 JAR		
2	NDC:68828-156-27	1 in 1 BOX		
2	NDC:68828-156-17	7 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/24/2012	

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

Revised: 5/2012

JAFRA COSMETICS INTERNATIONAL