

**CALM DYNAMICS GENTLE HYDRATING DAY 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.

CALM DYNAMICS GENTLE HYDRATING DAY CREAM SPF 15

SUNSCREEN ACTIVE INGREDIENT (SPF 15):

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

PURPOSE: SUNSCREEN

OTHER INGREDIENTS: WATER/AQUA, HYDROXYETHYL ACRYLATE/SODIUM
ACRYLOYLDIMETHYLTAURATE COPOLYMER, SQUALANE, POLYSORBATE 60, TRIDECYL
NEOPENTANOATE, ALUMINUM STARCH OCTENYLSUCCINATE, SACCHARIDE
ISOMERATE, BUTYLENE GLYCOL, AVENA SATIVA (OAT) KERNEL EXTRACT,
POLYACRYLAMIDE, C13-14 ISOPARAFFIN, LURETH-7, HEMIDESMUS INDICUS EXTRACT,
PHYLLANTHUS EMBLICA EXTRACT, GLYCYRRHIZA GLABRA (LICORICE) EXTRACT,
DMDM HYDANTOIN, BIOSACCHARIDE GUM-4, CHONDRUS CRISPUS (CARRAGEENAN)
EXTRACT, PANTHENOL, TOCOPHERYL ACETATE, DIMETHICONE, PUERARIA LOBATA
ROOT EXTRACT, PEG-4 LAURATE, IODOPROPYNYL BUTYLCARBAMATE, TRISODIUM
EDTA, PENTYLENE GLYCOL, PROPAMIDOBENZOIC ACID.

GENTLE HYDRATING DAY 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.

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GENTLE HYDRATING DAY CREAM SPF 15



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GENTLE HYDRATING DAY CREAM SPF 15

CREMA FACIAL HIDRATANTE DE DÍA PARA
PIELES SENSIBLES CON FPS 15

WITH 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, Hydroxyethyl Acrylate/ Sodium Acryloyldimethyltaurate Copolymer, Squalane, Polysorbate 60, Tridecyl Neopentanoate, Aluminum Starch Octenylsuccinate, Saccharide Isomerate, Butylene Glycol, Avena Sativa (Oat) Kernel Extract, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Hemidesmus Indicus Extract, Phyllanthus Emblica Extract, Glycyrrhiza Glabra (Licorice) Extract, DMDM Hydantoin, Biosaccharide Gum-4, Chondrus Crispus (Carrageenan) Extract, Panthenol, Tocopheryl Acetate, Dimethicone, Pueraria Lobata Root Extract, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Trisodium EDTA, Pentylene Glycol, Propamidobenzoic Acid.

INGREDIENTES: Agua, Metoxicinamato de Octilo, Copolímero de Hidroxietil acrilato/Acriloildimetil taurato de sodio, Escualano, Polisorbato 60, Salicilato de Octilo, Neopentanoato de Tridecilo, Almidón-Octenilsuccinato de Aluminio, Isomerato de Sacáridos, Benzofenona-3, Butilenglicol, Extracto de Semilla de Avena (Avena sativa), Poliacrilamida, Isoparafina C13-14, Lauret-7, Extracto de Hemidesmus Indicus, Extracto de Phyllanthus Emblica, Extracto de Regaliz (Glycyrrhiza glabra), Hidantoína DMDM, Biosacárido Goma-4, Extracto de carragenina (Chondrus crispus), Pantenol, Acetato de Tocoferilo, Dimeticona, Extracto de Raíz de Pueraria Lobata, PEG-4 Laurato, Yodopropinil Butilcarbamato, EDTA Trisódico, Pentilén Glicol, Ácido Propamidobenzóico.



CALMING DYNAMICS



GENTLE HYDRATING DAY CREAM SPF 15

CREMA FACIAL HIDRATANTE DE DÍA
PARA PIELES SENSIBLES CON FPS 15

WITH INTELLISHIELD

Milde feuchtigkeitsspendende Tagescreme SPF 15
Crema Idratante da Giorno SPF15 per Pelli Sensibili

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.

50 ml e 1.7 FL OZ (US)

CALM DYNAMICS GENTLE HYDRATING DAY SPF 15

octinoxate octisalate oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-155
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4 g in 100 mL
OXYBENZONE (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
TRIDECYL NEOPENTANOATE (UNII: 3Z8H1DA7J5)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
OAT (UNII: Z6J799EAJK)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
HEMIDESMUS INDICUS ROOT (UNII: Y5CFT48S90)	
BIO SACCHARIDE GUM-1 (UNII: BB4PU4V09H)	
PHYLLANTHUS EMBLICA FRUIT (UNII: YLX4CW2576)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PUERARIA MONTANA VAR. LOBATA ROOT (UNII: PET93F4I3C)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:68828-155-12	1 in 1 BOX		
1	NDC:68828-155-62	50 mL in 1 JAR		
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

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