

**CALMING DYNAMICS 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.*

-----  
**CALMING DYNAMICS**

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.

JAFRA

CALMING DYNAMICS

GENTLE HYDRATING DAY CREAM SPF 15



# JAFRA

## CALMING DYNAMICS



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)

# CALMING DYNAMICS SPF 15

octinoxate octisalate oxybenzone cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-055
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 BUTYLCARBAMATE (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 PROPAMIDOBENZOIC ACID (UNII: 25KRT26H77)	
PEG-4 LAURATE (UNII: AYP4VM3N1Z)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:68828-055-12	1 in 1 BOX		
1	NDC:68828-055-62	50 mL in 1 JAR		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part352	04/24/2012		

**Labeler** - JAFRA COSMETICS INTERNATIONAL (041676479)

**Registrant** - JAFRA COSMETICS INTERNATIONAL (041676479)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture

Revised: 5/2012

JAFRA COSMETICS INTERNATIONAL