

**HARMONY DYNAMICS FACIAL BOOSTING 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.*

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**HARMONY DYNAMICS FACIAL BOOSTING CREAM SPF-15**

SUNSCREEN ACTIVE INGREDIENT (SPF 15):

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

PURPOSE: SUNSCREEN

**INGREDIENTS:** WATER/AQUA, CETEARYL ALCOHOL, CETEARETH-20, GLYCERIN, STEARYL STEARATE, MYRISTYL MYRISTATE, GARCINIA INDICA SEED BUTTER, SODIUM PCA, CYCLOMETHICONE, DIMETHICONOL, PENTYLENE GLYCOL, BIS-DIGLYCERYL POLYACRYLADIPATE-2, BUTYROSPERMUM PARKII (SHEA BUTTER) FRUIT, CASTANEA SATIVA (CHESTNUT) EXTRACT, GLYCYRRHIZA GLABRA (LICORICE) EXTRACT, MORINGA OLIEFERA EXTRACT, VETIVERA ZINZANOIDS (KHUS ROOT) EXTRACT, WITHANIA SOMNIFERIA (WINTER CHERRY) EXTRACT, MENTHA PIPERTITA (PEPPERMINT) EXTRACT, CERAMIDE 2, PEG 10 BRASSICA CAMESTRIS STEROL, PALMITOYL OLIGOPEPTIDE, C12-15 ALKYL BENZOATE, TRIBEHENIN, CETYL ALCOHOL, PHENOXYETHANOL, METHYLPARABEN, ETHYLPARABEN, PROPYLPARABEN, BUTYLPARABEN, TOCOPHEROL, GLYCEINE SOJA (SOYBEAN) ISOFLAVONE AGLYONE, LECITHIN, POLYSORBATE 80, ALCOHOL, FRAGRANCE/PARFUM, TRIETHANOLAMINE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, DMDM HYDANTOIN, PANTHENOL, BIOSACCHARIDE GUM-4, CHONDRUS CRISPUS (CARRAGEENAN) EXTRACT, PEG-4 LAURATE, IODOPROPYL BUTYLCARBAMATE, TRISODIUM EDTA.

A LUXURIOUS RICH CREAM FOR COMPLEXIONS AFFECTED BY HORMONAL IMBALANCES AND AGING WHICH CAN MAKE THE SKIN DRY AND LACK VITALITY.

THIS UNIQUE FORMULA HELPS SOOTHE AND SMOOTH THE SKIN WHILE FIGHTING AGAINST SIGNS OF AGING AND CONTAINS A PRO-ENDORPHIN COMPLEX THAT HELPS PROVIDE A PLEASURABLE SENSATION TO THE SKIN, CREATING A VISIBLE APPEARANCE OF REFRESHED, YOUNGER AND MORE RADIANT LOOKING SKIN.

TO USE: SMOOTH OVER FACE AND THROAT DAY AND NIGHT AFTER CLEANSING.

CAUTION: FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES.

DISCONTINUE USE IF SIGNS OF IRRITATION APPEAR.

KEEP OUT OF REACH OF CHILDREN.

CLINICALLY, ALLERGY, IRRITANCY AND DERMATOLOGIST TESTED.

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HARMONY DYNAMICS

FACIAL BOOSTING CREAM SPF 15

WITH / CON INTELLISHIELD



JAFRA

**HARMONY DYNAMICS**



FACIAL BOOSTING CREAM SPF 15

CREMA FACIAL NUTRITIVA CON \*FPS 15

**WITH / CON INTELLISHIELD**

50 ml e 1.7 FL OZ (US)

## **Boosting Creme SPF 15**

### **Crema Rivitalizzante per il Viso SPF 15**

**To use:** Smooth over face and throat day and night after cleansing. Clinically, allergy, irritancy and dermatologist tested. **Cautions:** For external use only. Avoid contact with eyes. Discontinue use if signs of irritation appear. Keep out of reach of children.

**Instrucciones de uso:** Aplicar suavemente en rostro y cuello, por la mañana y por la noche, después de la limpieza. Clínica y dermatológicamente probada contra alergia e irritación.

**Precauciones:** Sólo para uso externo. Evite el contacto con los ojos. Descontinúe su uso si hubiere irritación. No se deje al alcance de los niños. **\*FPS: Factor de Protección Solar.**

**Anwendung:** Morgens und abends nach der Reinigung auf Gesicht und Hals auftragen.

Auf Allergien und Irritationen klinisch und dermatologisch getestet.

**Warnung:** Nur für die äußere Anwendung bestimmt. Den Kontakt mit den Augen vermeiden. Wenn Hautirritationen auftreten, Anwendung abbrechen. Von Kindern fern halten.

**Uso:** Stendere sul viso e sul collo, mattino e sera, dopo il detergente. Clinicamente testato contro allergia e irritazione. **Attenzione:** Solo per uso esterno. Evitare il contatto con gli occhi. Sospendere l'uso in caso di irritazione. Mantenere fuori dalla portata dei bambini.

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.

Contiene **INTELLISHIELD**, uno speciale complesso ad alta tecnologia che agisce come una pellicola invisibile, imitando la vera pelle.

**INGREDIENTS:** SUNSCREEN ACTIVE INGREDIENTS (SPF 15): Octinoxate, Octisalate, Oxybenzone/Benzophenone-3. OTHER INGREDIENTS: Water/Aqua, Cetearyl Alcohol, Ceteareth-20, Glycerin, Stearyl Stearate, Myristyl Myristate, Garcinia Indica Seed Butter, Sodium PCA, Cyclomethicone, Dimethiconol, Pentylene Glycol, Bis-Diglyceryl Polyacyladipate-2, Butyrospermum Parkii (Shea Butter) Fruit, Castanea Sativa (Chestnut) Extract, Glycyrrhiza Glabra (Licorice) Extract, Moringa Oleifera Extract, Vetivera Zinzanoids (Khus Root) Extract, Withania Somniferia (Winter Cherry) Extract, Mentha Piperita (Peppermint) Extract, Ceramide 2, PEG 10 Brassica Campestris Sterol, Palmitoyl Oligopeptide, C12-15 Alkyl Benzoate, Tribehenin, Cetyl Alcohol, Phenoxyethanol, Methylparaben, Ethylparaben, Propylparaben, Butylparaben, Tocopherol, Glycine Soja (Soybean) Isoflavone Aglycone, Lecithin, Polysorbate 80, Alcohol, Fragrance/Parfum, Triethanolamine, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, DMDM Hydantoin, Panthenol, Biosaccharide Gum-4, Chondrus Crispus (Carrageenan) Extract, PEG-4 Laurate, Iodopropynyl Butylcarbamate, Trisodium EDTA .

**INGREDIENTES:** Agua, Metoxicinamato de Octilo, Alcohol Cetearílico, Cetearet-20, Salicilato de Octilo, Glicerina, Estearato de Estearilo, Miristato de Miristilo, Benzofenona-3, Manteca de Semilla de Kokam (Garcinia Indica), PCA Sódico, Ciclometicona, Dimeticonol, Pentilen Glicol, Bis-Digliceril Poliaciladipato-2, Manteca de Karité (Butyrospermum Parkii) , Extracto de Castaño (Castanea Sativa), Extracto de Regaliz (Glycyrrhiza Glabra), Extracto de Moringa Oleifera, Extracto de Vetiver (Vetivera Zinzanoids), Extracto de Withania Somniferia, Extracto de Menta Piperita (Mentha piperita), Ceramida 2, PEG 10 Esterol de Brassica Campestris, Palmitoil Oligopéptido, C12-15 Alquil Benzoato, Tribehenina, Alcohol Cetílico, Fenoxietanol, Metilparabeno, Etilparabeno, Propilparabeno, Butilparabeno, Tocoferol, Isoflavona Agliona de Soya (Glycine Soja), Lecitina, Polisorbato 80, Alcohol, Fragancia, Trietanolamina, Crosolímero de Acrilatos/C10-30 Alquil Acrilato, Hidantoína DMDM, Pantenol, Biosacárido Goma-4, Extracto de Carragenina (Chondrus crispus), PEG-4 Laurato, Yodopropinil Butilcarbarnato, EDTA Trisódico.

Contains: Oxybenzone / Enthält Oxybenzon / Contiene: Oxybenzone.

A luxurious rich cream for complexions affected by hormonal imbalances and aging which can make the skin dry and lack vitality. This unique formula helps soothe and smooth the skin while fighting against signs of aging and contains a pro-endorphin complex that helps provide a pleasurable sensation to the skin, creating a visible appearance of refreshed, younger and more radiant looking skin.

Crema de rica textura ideal para pieles que se han visto afectadas por desbalances hormonales o envejecimiento cronológico, lo que da como resultado resequedad y falta de vitalidad en la piel. Esta formulación única ayuda a suavizar la piel mientras ayuda a combatir los signos de envejecimiento, además de que contiene un complejo de pro-endorfinas que ayuda a crear una sensación placentera en la piel, favoreciendo una apariencia juvenil y radiante.

Diese wertvolle und reichhaltige Creme pflegt die Haut, die durch den natürlichen Alterungsprozess besonders beansprucht ist. Dies zeigt sich vor allem an einem trockenen Hautbild, das an Vitalität verliert. Diese einzigartige Formel beruhigt die Haut, macht sie weicher und wirkt den Zeichen der Hautalterung entgegen. Beinhaltet einen Pro-Endorphin Komplex, der dabei hilft, der Haut ein angenehmes Gefühl zu verleihen sowie die Haut frischer, jünger und entspannter aussehen zu lassen.

Ricca crema per carnagioni interessate da disequilibri ormonali e da un invecchiamento dovuto all'età, che causi alla pelle secchezza e perdita di vitalità. Questa formula unica aiuta efficacemente a rendere la pelle liscia e morbida, combattendo al tempo stesso i segni dell'invecchiamento, e contiene un complesso di pro-endorfina che aiuta la pelle a raggiungere una situazione di benessere, creando un aspetto visivo di pelle rinfrescata, piú giovane, rilassata e radiosa.

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|---|---|
|  | <b>HARMONY DYNAMICS</b>   |
| <b>JAFRA</b>  |  |
|   | <b>FACIAL BOOSTING<br/>CREAM SPF 15</b>   |
|   | <hr/>   |
|   | <b>CREMA FACIAL<br/>NUTRITIVA CON FPS 15</b>  |
| <b>WITH / CON INTELLISHIELD</b>   |   |
| <b>Boosting Creme SPF 15</b>  |   |
| <b>Crema Rivitalizzante per il Viso SPF 15</b>                                      |   |
| <b>50 ml e 1.7 FL OZ (US)</b>   |   |

# HARMONY DYNAMICS FACIAL BOOSTING SPF 15

octinoxate octisalate oxybenzone cream

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68828-163 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength      |
|---|-------------------|---------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)     | OCTINOXATE        | 7 g in 100 mL |
| <b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE        | 4 g in 100 mL |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)   | OXYBENZONE        | 2 g in 100 mL |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>WATER</b> (UNII: 059QF0K00R)                          |          |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)            |          |
| <b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)  |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                       |          |
| <b>STEARYL STEARATE</b> (UNII: 5WX2EGD0DK)               |          |
| <b>MYRISTYL MYRISTATE</b> (UNII: 4042ZC00DY)             |          |
| <b>GARCINIA INDICA SEED BUTTER</b> (UNII: US2H3D7800)    |          |
| <b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2) |          |
| <b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)                 |          |
| <b>DIMETHICONOL (250000 MW)</b> (UNII: RKI3S914RT)       |          |
| <b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)               |          |
| <b>DIGLYCERIN</b> (UNII: 3YC120743U)                     |          |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                    |          |
| <b>SPANISH CHESTNUT</b> (UNII: 2MT5XMR2YW)               |          |
| <b>LICORICE</b> (UNII: 61ZBX54883)                       |          |
| <b>MORINGA OLEIFERA LEAF</b> (UNII: 4WET1AWO9B)          |          |
| <b>VETIVERIA ZIZANIOIDES ROOT</b> (UNII: 37TB8LUP9Z)     |          |
| <b>WITHANIA SOMNIFERA LEAF</b> (UNII: J337CNM3CW)        |          |
| <b>PEPPERMINT</b> (UNII: V95R5KMY2B)                     |          |
| <b>CERAMIDE 2</b> (UNII: C04977SRJ5)                     |          |
| <b>CAMPESTEROL</b> (UNII: 5L5O665639)                    |          |
| <b>PALMITOYL OLIGOPEPTIDE</b> (UNII: HO4ZT5S86C)         |          |
| <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)        |          |
| <b>TRIBEHENIN</b> (UNII: 8OC9U7TQZ0)                     |          |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)                  |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                 |          |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)                  |          |
| <b>ETHYLPARABEN</b> (UNII: 14255EXE39)                   |          |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)                  |          |

|   |
|---|
| BUTYL PARABEN (UNII: 3QPI1U3FV8)                              |
| TOCOPHEROL (UNII: R0ZB2556P8)                                 |
| SOYBEAN (UNII: L7HT8FIZOD)                                    |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62)                          |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)                             |
| ALCOHOL (UNII: 3K9958V90M)                                    |
| TROLAMINE (UNII: 9O3K93S3TK)                                  |
| CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO) |
| DMDM HYDANTOIN (UNII: BYR0546TOW)                             |
| PANTHENOL (UNII: WV9CM0O67Z)                                  |
| BIO SACCHARIDE GUM-1 (UNII: BB4PU4V09H)                       |
| CHONDRUS CRISPUS (UNII: OQS23HUA1X)                           |
| PEG-4 LAURATE (UNII: AYP4VM3N1Z)                              |
| IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)               |
| EDETATE TRISODIUM (UNII: 420IP921MB)                          |

| Packaging |                  |                     |                      |                    |
|-----------|------------------|---------------------|----------------------|--------------------|
| #         | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1         | NDC:68828-163-12 | 1 in 1 BOX          |                      |                    |
| 1         | NDC:68828-163-62 | 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                                  | 04/19/2012           |                    |

**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         |