

BRIGHTENING AND MOISTURIZING FACIAL SPF 30- avobenzone, ensulizole, octisalate, octocrylene, and oxybenzone lotion

Ventura International LTD

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.

Brightening and moisturizing facial lotion SPF 30

Drug Facts

| Active Ingredients | Purpose |
|---------------------------|----------------|
| AVOBENZONE 3.00% | Sunscreen |
| ENSULIZOLE 3.00 % | Sunscreen |
| OCTISALATE 5.00 % | Sunscreen |
| OCTOCRYLENE 5.00 % | Sunscreen |
| OXYBENZONE 6.00 % | Sunscreen |

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.
- **For external use only.**
- **Do not use** on damaged or broken skin.
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor if** rash occurs.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

WATER, DICAPRYLYL CARBONATE, CETEARYL ALCOHOL, PHENETHYL BENZOATE, TRIETHANOLAMINE, CYCLOPENTASILOXANE, PROPYLENE GLYCOL, METHYL

METHACRYLATE CROSSPOLYMER, SORBITAN STEARATE, TRIETHYLHEXANOIN, POTASSIUM CETYL PHOSPHATE, PHENOXYETHANOL, DIMETHICONE, STEARYL DIMETHICONE, CETEARETH-20, XANTHAN GUM, CETYL ALCOHOL, GLYCERYL STEARATE, CHLORPHENESIN, FRAGRANCE, VIGNA ACONITIFOLIA SEED EXTRACT, DIMETHYLMETHOXY CHROMANYL PALMITATE, PEG-75 STEARATE, SODIUM COCOYL GLUTAMATE, TETRASODIUM EDTA, CETETH-20, STEARETH-20, BUTYLPARABEN, SORBIC ACID, METHYLPARABEN, ALPHA-ISOMETHYL IONONE, HYDROXYCITRONELLAL, d-LIMONENE, LINALOOL, BENZYL SALICYLATE, CITRONELLOL.

Dist. by Ventura Int Ltd. DBA Belcorp
USA, Miami, FL 33126

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box

L'BEL
DERMO CLARITÉ

brightening and moisturizing **facial**
lotion SPF 30

30 ml e (1 fl.oz.)

www.lbel.com

L'BEL

DERMO CLARITÉ

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Other information

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Inactive ingredients: water, dicaprylyl carbonate, cetearyl alcohol, phenethyl benzoate, triethanolamine, cyclopentasiloxane, propylene glycol, methyl methacrylate crosspolymer, sorbitan stearate, triethylhexanoin, potassium cetyl phosphate, phenoxyethanol, dimethicone, stearyl dimethicone, cetareth-20, xanthan gum, cetyl alcohol, glyceryl stearate, chlorphenesin, fragrance, vigna aconitifolia seed extract, dimethylmethoxy chromanyl palmitate, peg-75 stearate, sodium cocoyl glutamate, tetrasodium edta, ceteth-20, steareth-20, butylparaben, sorbic acid, methylparaben, alpha-isomethyl ionone, hydroxycitronellal, d-limonene, linalool, benzyl salicylate, citronellol.

brightening and moisturizing facial lotion SPF 30
loción facial iluminadora hidratante con FPS 30

U.S.A.: Dist. by Ventura Int. Ltd., DBA Solcorp
USA: Miami, FL 33128 Made in Colombia
PUERTO RICO: Dist. by Ventura Corp. Ltd.,
San Juan, Puerto Rico 00926. Made in
Colombia
Formulated in France

30 ml e (1 fl.oz.)

BRIGHTENING AND MOISTURIZING FACIAL SPF 30
avobenzone, ensulizole, octisalate, octocrylene, and oxybenzone lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:14783-971 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|--|--------------------------|-----------------|
| Ingredient Name | | Basis of Strength | Strength |
| Avobenzonone (UNII: G63QQF2NOX) (Avobenzonone - UNII:G63QQF2NOX) | | Avobenzonone | 0.03 g in 1 mL |
| Ensulizole (UNII: 9YQ9DIIW42) (Ensulizole - UNII:9YQ9DIIW42) | | Ensulizole | 0.03 g in 1 mL |
| Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W) | | Octisalate | 0.05 g in 1 mL |
| Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM) | | Octocrylene | 0.05 g in 1 mL |
| Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y) | | Oxybenzone | 0.06 g in 1 mL |

| Inactive Ingredients | | Strength |
|--|--|-----------------|
| Ingredient Name | | |
| WATER (UNII: 059QF0KO0R) | | |
| DICAPRYLYL CARBONATE (UNII: 609A3V1SUA) | | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS) | | |
| PHENETHYL BENZOATE (UNII: 0C143929GK) | | |
| TROLAMINE (UNII: 9O3K93S3TK) | | |
| CYCLOMETHICONE 5 (UNII: 0THT5PC10R) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X) | | |
| TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K) | | |
| POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT) | | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | | |
| STEARYL DIMETHICONE (400 MPAS AT 50C) (UNII: R327X197HY) | | |
| POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY) | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | | |
| CHLORPHENESIN (UNII: I670DAL4SZ) | | |
| MOTH BEAN (UNII: H7938ON8E5) | | |
| DIMETHYLMETHOXY CHROMANYL PALMITATE (UNII: 5G222ZDK7U) | | |
| PEG-75 STEARATE (UNII: OT38R0N74H) | | |
| SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG) | | |
| EDETATE SODIUM (UNII: MP1J8420LU) | | |
| CETETH-20 (UNII: I835H2IHHX) | | |
| STEARETH-20 (UNII: L0Q8IK9E08) | | |
| BUTYL PARABEN (UNII: 3QPII03FV8) | | |
| SORBIC ACID (UNII: X045WJ989B) | | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | | |
| ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B) | | |
| HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR) | | |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | | |
| LINALOOL, (+/-)- (UNII: D81QY6I88E) | | |
| BENZYL SALICYLATE (UNII: WAO5MKN9TU) | | |
| .BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K) | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:14783-971-02 | 1 in 1 BOX | 09/26/2016 | |
| 1 | NDC:14783-971-01 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 09/26/2016 | |

Labeler - Ventura International LTD (603192787)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| Bel Star S.A. (Colombia) | | 880160197 | MANUFACTURE(14783-971) |

Revised: 9/2016

Ventura International LTD