

**L'BEL DERMO CLARITE BRIGHTENING AND MOISTURIZING FACIAL SPF 30-
avobenzone, octisalate, and octocrylene 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.

L'BEL DERMO CLARITÉ BRIGHTENING AND MOISTURIZING FACIAL LOTION SPF 30

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Avobenzone 1.80 %	Sunscreen
Octisalate 4.50 %	Sunscreen
Octocrylene 4.50 %	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, GLYCERIN, C12-15 ALKYL BENZOATE, BUTYLOCTYL SALICYLATE, CYCLOHEXASILOXANE, ETHYLHEXYL METHOXYCRYLENE, POTASSIUM CETYL PHOSPHATE, TRIETHYLHEXANOIN, HYDROGENATED PALM GLYCERIDES, GLYCERYL

STEARATE, PEG-100 STEARATE, SYNTHETIC FLUORPHLOGOPITE,
HYDROXYACETOPHENONE, TITANIUM DIOXIDE, ACRYLATES/C10-30 ALKYL ACRYLATE
CROSSPOLYMER, VIGNA ACONITIFOLIA SEED EXTRACT, XANTHAN GUM, 1,2-
HEXANEDIOL, CAPRYLYL GLYCOL, DIMETHYLMETHOXY CHROMANYL PALMITATE,
CETEARYL ISONONANOATE, SODIUM COCOYL GLUTAMATE, ACACIA SENEGAL GUM,
TETRASODIUM EDTA, CETEARETH-20, CETEARYL ALCOHOL, SODIUM HYDROXIDE,
HYDROLYZED ALGIN, CETEARETH-12, CETYL PALMITATE, PHENOXYETHANOL, TIN
OXIDE

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

PRINCIPAL DISPLAY PANEL - 30 ml Jar Box

L'BEL

DERMO
CLARITÉ

brightening and
moisturizing facial
lotion SPF 30

30 ml e (1 fl.oz.)

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Octocrylene 4.50% Sunscreen

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Other Information

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Inactive Ingredients

Water, glycerin, c12-15 alkyl benzoate, butyloctyl salicylate, cyclohexasiloxane, ethylhexyl methoxycrylene, potassium cetyl phosphate, triethylhexanoin, hydrogenated palm glycerides, glyceryl stearate, peg-100 stearate, synthetic fluorphlogopite, hydroxyacetophenone, titanium dioxide, acrylates/c10-30 alkyl acrylate crosspolymer, vigna aconitifolia seed extract, xanthan gum, 1,2-hexanediol, caprylyl glycol, dimethylmethoxy chromanyl palmitate, cetearyl isononanoate, sodium cocoyl glutamate, acacia senegal gum, tetrasodium edta, ceteareth-20, cetearyl alcohol, sodium hydroxide, hydrolyzed algin, ceteareth-12, cetyl palmitate, phenoxyethanol, tin oxide.

U.S.A.: Dist. by Ventura Int Ltd, DBA Belcorp
USA, Miami, FL 33126 Made in Colombia.
PUERTO RICO: Dist. by Ventura Corp, Ltd.,
San Juan, Puerto Rico 00926. Made in
Colombia.

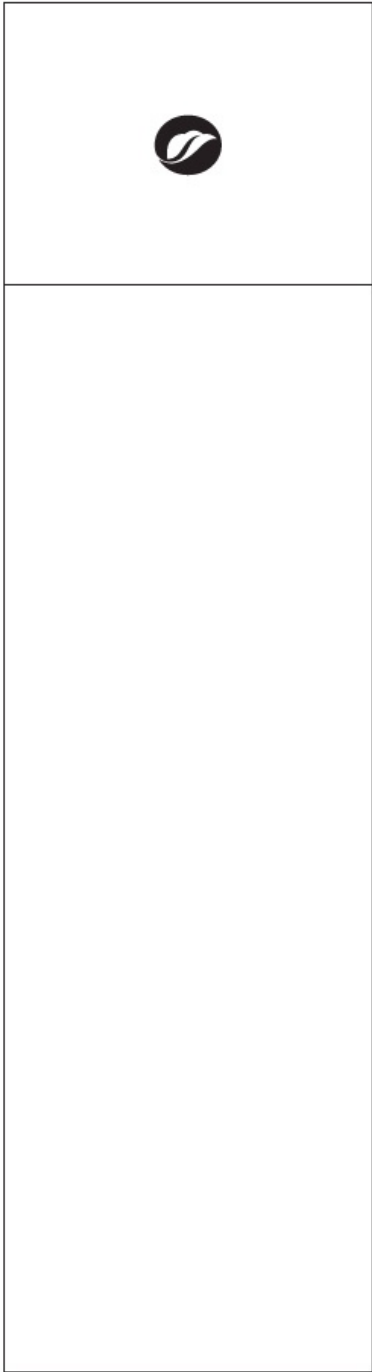
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DERMO
CLARITÉ

locion facial
iluminadora
hidratante con FPS 30

brightening and
moisturizing facial
lotion SPF 30

30 ml e (1 fl.oz.)



LBEL DERMO CLARITE BRIGHTENING AND MOISTURIZING FACIAL SPF 30

avobenzone, octisalate, and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-129
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.018 g in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.045 g in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.045 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHYLMETHOXY CHROMANYL PALMITATE (UNII: 5G222ZDK7U)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	
ACACIA (UNII: 5C5403N26O)	
EDETATE SODIUM (UNII: MP1J8420LU)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STANNIC OXIDE (UNII: KM7N50LOS6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-129-01	1 in 1 BOX	08/08/2018	
1		30 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/08/2018	

Labeler - Ventura International LTD (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-129)

Revised: 8/2018

Ventura International LTD