

LBEL DERMO CLARITE- 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.

L'BEL
DERMO CLARITÉ

Drug Facts

Active Ingredients

Butyl methoxydibenzoylmethane 3.0%,
Ensulizole 3.0%,
Octisalate 5.0%,
Octocrylene 5.0%,
Oxybenzone 6.0%

Purpose

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 damage 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.
- Children under 6 months of age: Ask a doctor
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.

Other information

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

Inactive ingredients

aqua (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, chlorphenesin, parfum (fragrance), vigna aconitifolia seed extract, cetyl alcohol, dimethylmethoxy chromanyl palmitate, glyceryl stearate, methylparaben, sodium cocoyl glutamate, tetrasodium edta, peg-75 stearate, butylparaben, sorbic acid, ceteth-20, steareth-20.

US: Distributed by Ventura International Ltd,
San Francisco, CA 94111.

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box**L'BEL**

DERMO CLARITÉ

clarifying and moisturizing
facial lotion with SPF 30

30 ml e (1 fl.oz.)

www.lbel.com

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loción facial aclaradora
hidratante con FPS 30

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US: Distributed by Ventura International, Ltd.
San Francisco, CA 94111. Made in Colombia.
PR: Distributed by Ventura Corporation, Ltd.
San Juan, Puerto Rico 00925.
Made in Colombia.
FORMULATED IN FRANCE
Made in Colombia

L'BEL DERMOCLEARITE

avobenzone, ensulizole, octisalate, octocrylene, and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-434
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: 9YQ9D11W42) (Ensulizole - UNII:9YQ9D11W42)	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

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
dicaprylyl carbonate (UNII: 609A3V1SUA)	
alcohol (UNII: 3K9958V90M)	
phenethyl benzoate (UNII: 0C143929GK)	
trolamine (UNII: 9O3K93S3TK)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
propylene glycol (UNII: 6DC9Q167V3)	
sorbitan monostearate (UNII: NVZ4I0H58X)	
triethylhexanoic acid (UNII: 7K3W1BIU6K)	
potassium cetyl phosphate (UNII: 03KCY6P7UT)	
phenoxyethanol (UNII: HIE492ZZ3T)	
dimethicone (UNII: 92RU3N3Y1O)	
polyoxyl 20 cetostearyl ether (UNII: YRC528SWUY)	
xanthan gum (UNII: TTV12P4NEE)	
chlorphenesin (UNII: I670DAL4SZ)	
moth bean (UNII: H7938ON8E5)	
cetyl alcohol (UNII: 936JST6JCN)	
glyceryl monostearate (UNII: 230OU9XXE4)	
methylparaben (UNII: A218C7H9T)	
edetate sodium (UNII: MP1J8420LU)	
peg-75 stearate (UNII: OT38R0N74H)	
butylparaben (UNII: 3QPI1U3FV8)	
sorbic acid (UNII: X045WJ989B)	
ceteth-20 (UNII: I835H2IHHX)	
steareth-20 (UNII: L0Q8IK9E08)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-434-01	1 in 1 BOX		
1	NDC:14783-434-02	30 mL in 1 BOTTLE		
2	NDC:14783-434-04	1 in 1 BOX		
2		3 mL in 1 BOTTLE		
3	NDC:14783-434-05	1 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	11/26/2011	

Labeler - Ventura International Ltd. (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star, S. A.(Colombia)		880160197	MANUFACTURE(14783-434)

Establishment

Name	Address	ID/FEI	Business Operations
Yobel Supply Chain Management (Peru)		934116930	MANUFACTURE(14783-434)

Revised: 11/2011

Ventura International Ltd.