

**LBEL DERMO CLARITE LOCION FACIAL ILUMINADORA HIDRATANTE CON FPS 30 BRIGHTENING AND MOISTURIZING FACIAL SPF 30- avobenzone, octisalate, octocrylene emulsion
BEL STAR S A**

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.

LBEL DERMO CLARITE LOCION FACIAL ILUMINADORA HIDRATANTE CON FPS 30 BRIGHTENING AND MOISTURIZING FACIAL LOTION SPF 30

Drug Facts

Active Ingredients

AVOBENZONE 1.80%

OCTISALATE 4.50%

OCTOCRYLENE 4.50%

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 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, cetearyl isononanoate, sodium cocoyl glutamate, acacia senegal gum, dimethylmethoxy chromanyl palmitate, tetrasodium edta, cetareth-20, cetearyl alcohol, sodium hydroxide, hydrolyzed algin, cetareth-12, cetyl palmitate, phenoxyethanol, tin oxide.

Company Information

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.

www.lbel.com

Product Packaging





LBEL DERMO CLARITE LOCION FACIAL ILUMINADORA HIDRATANTE CON FPS 30 BRIGHTENING AND MOISTURIZING FACIAL SPF 30

avobenzone, octisalate, octocrylene emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14141-315
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	18 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	45 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETARETH-12 (UNII: 7V4MR24V5P)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
MOTH BEAN (UNII: H7938ON8E5)	
XANTHAN GUM (UNII: TTV12P4NEE)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DISODIUM COCOYL GLUTAMATE (UNII: MBK0CP8F5A)	
DIMETHYLMETHOXY CHROMANYL PALMITATE (UNII: 5G222ZDK7U)	
EDETATE SODIUM (UNII: MP1J8420LU)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STANNOUS OXIDE (UNII: JB2MV9I3LS)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
ACACIA (UNII: 5C5403N26O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-315-01	1 in 1 BOX	10/13/2022	
1		30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/13/2022	

Labeler - BEL STAR S A (880160197)

Revised: 10/2022

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