

LBEL LEDERM DAY SUNSCREEN BROAD SPECTRUM SPF 15- avobenzone, 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 LEDERM DAY LOTION SUNSCREEN BROAD SPECTRUM SPF 15

Drug Facts

Active Ingredients	Purpose
AVOBENZONE 3.0%	Sunscreen
OCTISALATE 5.0 %	Sunscreen
OCTOCRYLENE 3.0 %	Sunscreen
OXYBENZONE 5.0 %	Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

- **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.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours
- Children under 6 months of age: Ask a doctor
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m.–2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses.

Other information

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

Inactive ingredients

WATER, C12-15 ALKYL BENZOATE, CYCLOHEXASILOXANE, GLYCERIN, POTASSIUM CETYL PHOSPHATE, ALBIZIA JULIBRISSIN BARK EXTRACT, DIMETHICONE, GLYCERYL STEARATE, PENTYLENE GLYCOL, METHYL METHACRYLATE CROSSPOLYMER, HYDROGENATED PALM GLYCERIDES, PHENOXYETHANOL, XANTHAN GUM, C20-22 ALKYL PHOSPHATE, ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER, FRAGRANCE, C20-22 ALCOHOLS, CHLORPHENESIN, HYDROLYZED CERATONIA SILIQUA SEED EXTRACT, SODIUM HYDROXIDE, ACACIA SENEGAL GUM, DISODIUM EDTA, OLIVE OIL AMINOPROPANEDIOL ESTERS, RASPBERRY SEED OIL/TOCOPHERYL SUCCINATE AMINOPROPANEDIOL ESTERS, HYDROXYPROPYL CYCLODEXTRIN, PALMITOYL TRIPEPTIDE-38.

USA: Dist. by Ventura International Ltd. DBA Belcorp USA,
San Francisco, CA 94111.

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Box

• FORMULATED BY FRENCH DERMATOLOGISTS
SKIN
EXPERTS

LEDERM

DAY LOTION

SUNSCREEN

BROAD SPECTRUM

SPF 15

day facial **lotion**

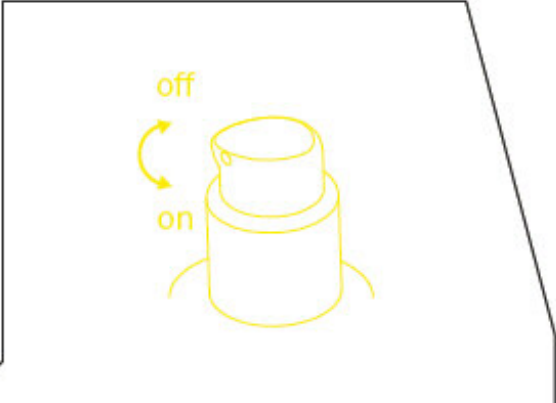
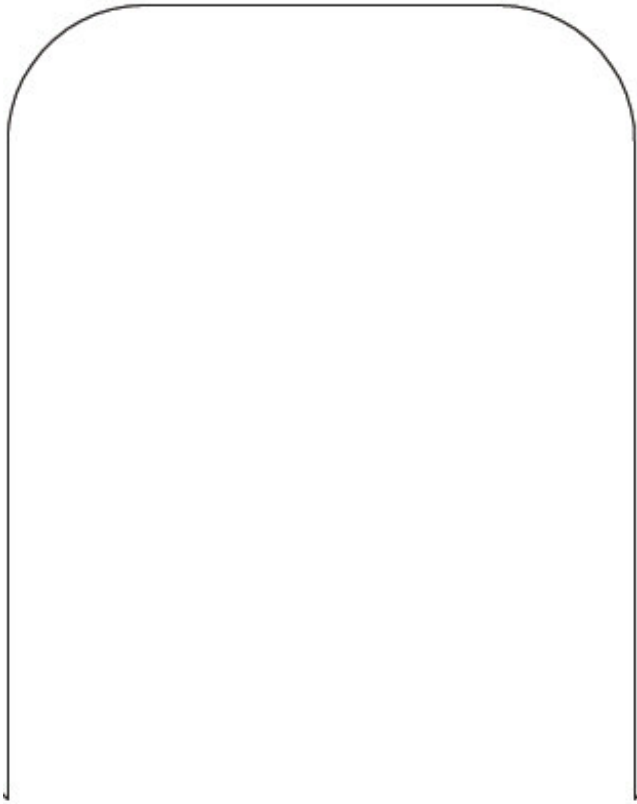
SPF 15 against

noticeable signs

of aging

normal to oily skin

50 ml e (1.6 fl.oz.)



Drug Facts (continued)

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Other information

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LEDERM

DAY LOTION

**SUNSCREEN
BROAD SPECTRUM
SPF 15**

day facial **lotion**
SPF 15 against
noticeable signs
of aging
normal to oily skin

50 ml e (1.6 fl.oz.)

from excessive heat and direct sun.

Inactive ingredients

water, c12-15 alkyl benzoate, cyclohexasiloxane, glycerin, potassium cetyl phosphate, albizia julibrissin bark extract, dimethicone, glyceryl stearate, pentylene glycol, methyl methacrylate crosspolymer, hydrogenated palm glycerides, phenoxyethanol, xanthan gum, c20-22 alkyl phosphate, acrylates/vinyl isodecanoate crosspolymer, fragrance, c20-22 alcohols, chlorphenesin, hydrolyzed ceratonia siliqua seed extract, sodium hydroxide, acacia senegal gum, disodium edta, olive oil aminopropanediol esters, raspberry seed oil/tocopheryl succinate aminopropanediol esters, hydroxypropyl cyclodextrin, palmitoyl tripeptide-38.

USA; Dist. by Ventura International Ltd. DBA Belcorp USA, San Francisco, CA 94111.

Formulated in France/Made in Colombia
Formulado en Francia/Hecho en Colombia

Pump with double seal protection preventing waste and air contact. It does not contain metallic pieces to prevent formula oxidation.

Dispensador con doble sello de protección: evita el desperdicio y el contacto con el aire. No contiene piezas metálicas para impedir la oxidación de la fórmula.



LEDERM

DAY LOTION

SUNSCREEN BROAD SPECTRUM SPF 15

loción facial de día
SPF 15 contra signos
evidentes de la edad
cutis normal a graso

50 ml e (1.6 fl.oz.)

Drug Facts

Active Ingredients	Purpose
Avobenzone 3.0 %	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 3.0%	Sunscreen
Oxybenzone 5.0%	Sunscreen

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LBEL LEDERM DAY SUNSCREEN BROAD SPECTRUM SPF 15

avobenzone, octisalate, octocrylene, and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-803
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	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	0.03 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.05 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
alkyl (c12-15) benzoate (UNII: A9EJ3J61HQ)	
cyclomethicone 6 (UNII: XHK3U310BA)	
glycerin (UNII: PDC6A3C0OX)	
potassium cetyl phosphate (UNII: 03KCY6P7UT)	
albizia julibrissin bark (UNII: 0J9G6W44DV)	
dimethicone (UNII: 92RU3N3Y1O)	
glyceryl monostearate (UNII: 230OU9XXE4)	
pentylene glycol (UNII: 50C1307PZG)	
hydrogenated palm glycerides (UNII: YCZ8EM144Q)	
phenoxyethanol (UNII: HIE492ZZ3T)	
xanthan gum (UNII: TTV12P4NEE)	
c20-22 alkyl phosphate (UNII: L4VKP0Y7RP)	
c20-22 alcohols (UNII: O4M0347C6A)	
chlorphenesin (UNII: I670DAL4SZ)	
sodium hydroxide (UNII: 55X04QC32I)	
acacia (UNII: 5C5403N26O)	
edetate disodium (UNII: 7FLD91C86K)	
palmitoyl lysyldioxymethionylllysine (UNII: T7A529FB8O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-803-02	1 in 1 BOX		
1	NDC:14783-803-01	50 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 FINAL	part352	06/22/2015	

Labeler - Ventura International LTD (603192787)**Establishment**

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-803)

Revised: 6/2015

Ventura International LTD