

LEDERM DAY SUNSCREEN BROAD SPECTRUM SPF 15 DAY FACIAL SPF 15 AGAINST NOTICEABLE SIGNS OF AGING ALL SKIN TYPES- avobenzone, octisalate, octocrylene, and oxybenzone lotion

Ventura International

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.

LEDERM DAY SUNSCREEN BROAD SPECTRUM SPF 15 day facial SPF 15 against noticeable signs of aging all skin types

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
AVOBENZONE 3%	Sunscreen
OCTISALATE 5%	Sunscreen
OCTOCRYLENE 3%	Sunscreen
OXYBENZONE 5%	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.

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

PRINCIPAL DISPLAY PANEL - 50 ml Bottle Box

• FORMULATED BY FRENCH DERMATOLOGISTS
SKIN
EXPERTS

LEDERM

DAY LOTION

SUNSCREEN

BROAD SPECTRUM

SPF 15

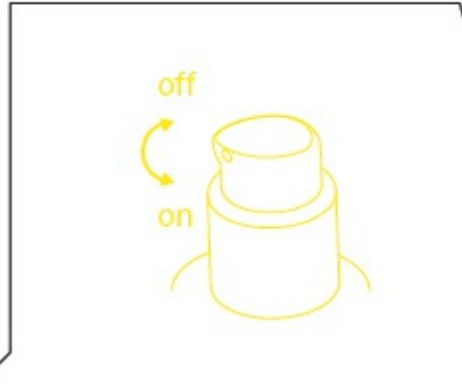
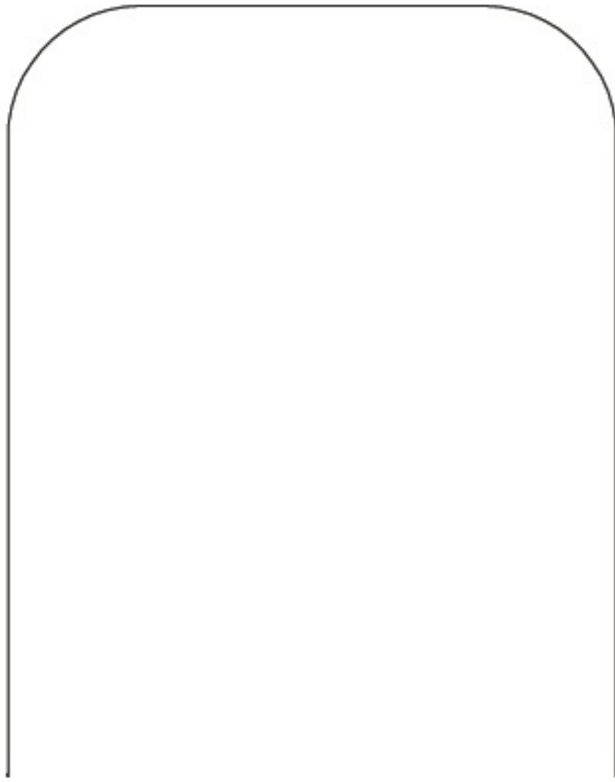
day **facial lotion**

SPF 15 against
noticeable signs

of aging

all skin types

50 ml e (1.6 fl.oz.)



LEDERM

Drug Facts (continued)

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DAY LOTION

SUNSCREEN
BROAD SPECTRUM
SPF 15

day **facial lotion**
SPF 15 against
noticeable signs
of aging
all skin types

50 ml e (1.6 fl.oz.)

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.

U.S.A.: Dist. by Ventura Int Ltd. DBA Belcorp USA, Miami, FL
33126 Made in Colombia

Formulated in France
Formulado en Francia

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
FPS 15 contra signos
evidentes de la edad
todo tipo de cutis

50 ml e (1.6 fl.oz.)

Drug Facts

Active Ingredients	Purpose
Avobenzone 3%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Octocrylene 3%.....	Sunscreen
Oxybenzone 5%.....	Sunscreen

Uses

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Warnings

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avobenzone, octisalate, octocrylene, and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-119
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	30 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	50 mg 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 ANHYDROUS (UNII: 8NLQ36F6MM)	
PALMITOYL LYSYLDIOMETHIONYLLYSINE (UNII: T7A529FB8O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:14783-119-02	1 in 1 BOX	09/15/2017	
1	NDC:14783-119-01	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		09/15/2017	

Labeler - Ventura International (603192787)

Establishment			
Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	manufacture(14783-119)

Revised: 2/2020

Ventura International