LBEL LEDERM 45PLUS JOUR SPF 15 FACIAL TREATMENT AGAINST NOTICEABLE SIGNS OF AGING DAY - NORMAL TO DRY SKIN- avobenzone, octis alate, octocrylene, and oxybenzone cream

Ventura Corporation 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 45plus Jour SPF 15 Facial Treatment Against Noticeable Signs of Aging Day - Normal to Dry Skin

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.

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

AQUA (WATER), C12-15 ALKYL BENZOATE, CYCLOHEXASILOXANE, GLYCERIN,

DIMETHICONE, POTASSIUM CETYL PHOSPHATE, ALBIZIA JULIBRISSIN BARK EXTRACT, BUTYLENE GLYCOL, GLYCERYL STEARATE, PENTYLENE GLYCOL, HYDROGENATED PALM GLYCERIDES, PHENOXYETHANOL, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, XANTHAN GUM, C20-22 ALKYL PHOSPHATE, ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER, PARFUM (FRAGRANCE), C20-22 ALCOHOLS, CHLORPHENESIN, HYDROLYZED CERATONIA SILIQUA SEED EXTRACT, ACACIA SENEGAL GUM, SODIUM HYDROXIDE, DISODIUM EDTA, OLIVE OIL AMINOPROPANEDIOL ESTERS, RASPBERRY SEED OIL/TOCOPHERYL SUCCINATE AMINOPROPANEDIOL ESTERS, HYDROXYPROPYL CYCLODEXTRIN, SILICA, PALMITOYL TRIPEPTIDE-38

P.R.: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 50 g Bottle Carton

L'BEL LEDERM

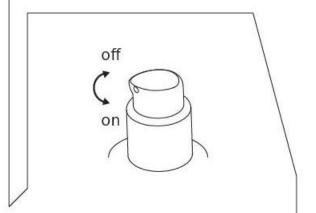
FORMULA CREATED BY FRENCH DERMATOLOGISTS **SKIN EXPERTS**

45+ JOUR

facial treatment against noticeable signs of aging day cream SPF 15 normal to dry skin

50 g e (1.7 oz.)

www.lbel.com



L'BEL LEDERM



Drug Facts (continued)

- 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

aqua (water), c12-15 alkyl benzoate, cycloh exasiloxane, glycerin, dimethicone, potassium cetyl phosphate, albizia julibrissin bark

45+ | JOUR

facial treatment against noticeable signs of aging day cream SPF 15 normal to dry skin

50 g e (1.7 oz.)

extract, butylene glycol, glyceryl stearate, pentylene glycol, hydrogenated palm glycerides, phenoxyethanol, hdi/trimethylol hexyllactone crosspolymer, xanthan gum, c20-22 alkyl phosphate, acrylates/ vinyl isodecanoate crosspolymer, parfum (fragrance), c20-22 alcohols, chlorphenesin, hydrolyzed ceratonia siliqua seed extract, acacia senegal gum, sodium hydroxide, disodium edta, olive oil aminopropanediol esters, raspberry seed oil/tocopheryl succinate aminopropanediol esters, hydroxypropyl cyclodextrin, silica, palmitoyl tripeptide-38.

US: Distributed by Ventura International Ltd. DBA Belcorp USA, San Francisco, CA 94111. Made in Colombia. P.R.: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Colombia.

Formulated in France Made in Colombia

> Pump with double seal protection preventing waste and air contact. Besides, it does not contain metallic pieces to prevent formula oxidization.

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



45+ | JOUR

tratamiento facial contra signos evidentes de la edad crema día FPS 15 cutis normal a seco

50 g e (1.7 oz.)

Drug Facts

Active Ingredients

Purpose

Avobenzone 3.0%, Octisalate 5.0%, Octocrylene 3.0%, Oxybenzone 5.0% Sunscreen

Uses

■ Helps prevent sunburn.

Warnings

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Discover more about LEDERM. Descubre más sobre LEDERM

LBEL LEDERM 45PLUS JOUR SPF 15 FACIAL TREATMENT AGAINST NOTICEABLE SIGNS OF AGING DAY - NORMAL TO DRY SKIN

avobenzone, octisalate, octocrylene, and oxybenzone cream

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Droduct	Informa	tion
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:13537-447

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 g		
Octisalate (UNII: 4X49 Y0596W) (Octisalate - UNII:4X49 Y0596W)	Octisalate	0.05 g in 1 g		
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.03 g in 1 g		
Oxybenzone (UNII: 9500S7VE0Y) (Oxybenzone - UNII:9500S7VE0Y)	Oxybenzone	0.05 g in 1 g		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HYDRO GENATED PALM GLYCERIDES (UNII: YCZ8 EM144Q)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
C20-22 ALKYL PHO SPHATE (UNII: L4VKP0 Y7RP)	
C20-22 ALCOHOLS (UNII: O4M0347C6A)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
ACACIA (UNII: 5C5403N26O)	
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	

I	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:13537-447-01	1 g in 1 PACKET	
2 NDC:13537-447-04	1 in 1 BOX	
2 NDC:13537-447-03	5 g in 1 BOTTLE, PLASTIC	
3 NDC:13537-447-06	1 in 1 BOX	
3 NDC:13537-447-05	50 g in 1 BOTTLE, GLASS	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/01/2013	

Labeler - Ventura Corporation LTD. (602751344)

Establishment			
Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-447)

Establishment			
Name	Address	ID/FEI	Business Operations
Yobel Supply Chain Management S.A. (Peru)		934116930	MANUFACTURE(13537-447)

Revised: 4/2013 Ventura Corporation LTD.