

L'BEL PROTEGE EXPERT- ensulizole, octinoxate, octisalate, oxybenzone, and titanium dioxide 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
PROTÈGE
EXPERT
moisturizing face
protector lotion
SPF 40**

Drug Facts

Active Ingredients

Ensulizole 3%,
Octinoxate 7.5%,
Octisalate 5%,
Oxybenzone 6%,
Titanium dioxide 3.9%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- Provides high protection against sunburn
- Retains SPF after 40 minutes of activity in the water

Warnings

For external use only.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash or irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally before sun exposure and as needed

Other information

- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

aqua (water), dicaprylyl carbonate, c12-15 alkyl benzoate, vp/eicosene copolymer, triethanolamine, methyl methacrylate crosspolymer, dimethicone, cyclopentasiloxane, cetearyl alcohol, sorbitan stearate, glyceryl stearate, potassium cetyl phosphate, tocopheryl acetate, cyclohexasiloxane, silica, trimethylsiloxysilicate, phenoxyethanol, methicone, cetareth-20, methylparaben, xanthan gum, mannitol, parfum (fragrance), propylparaben, butylparaben, ethylparaben, isobutylparaben, arginine, cyclodextrin, dextrin, faex extract (yeast extract), histidine hydrochloride (histidine hci), pisum sativum extract (pisum sativum (pea) extract), acetyltyrosine, disodium succinate, khaya senegalensis bark extract, nicotinamide adenine dinucleotide, pyridoxine hci, aspartic acid.

PRINCIPAL DISPLAY PANEL - 50 ml Carton

L'BEL

PROTÈGE EXPERT

moisturizing face
protector lotion
SPF 40

loción protectora
hidratante para rostro
FPS 40

WATER RESISTANT
RESISTENTE AL AGUA

50 ml e (1.7 fl.oz.)

UVB SPF

40

High Protection

UVA

PA + +

www.l'bel.com



L'BEL

• DERMATOLOGICALLY TESTED /
HYPOALLERGENIC

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Drug Facts (continued)

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

PROTÈGE EXPERT

moisturizing face
protector lotion
SPF 40

loción protectora
hidratante para rostro
FPS 40

WATER RESISTANT
RESISTENTE AL AGUA

50 ml e (1.7 fl.oz.)



LBEL PROTEGE EXPERT

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-304
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ensulizole (UNII: 9YQ9D11W42) (Ensulizole - UNII:9YQ9D11W42)	Ensulizole	.03 g in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	.075 g in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	.05 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	.06 g in 1 mL
Titanium dioxide (UNII: 15FIX9V2JP) (Titanium dioxide - UNII:15FIX9V2JP)	Titanium dioxide	.039 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
dicaprylyl carbonate (UNII: 609A3V1SUA)	
alkyl (c12-15) benzoate (UNII: A9EJ3J61HQ)	
dimethicone (UNII: 92RU3N3Y1O)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
sorbitan monostearate (UNII: NVZ4I0H58X)	
glyceryl monostearate (UNII: 230OU9XXE4)	
potassium cetyl phosphate (UNII: 03KCY6P7UT)	
cyclomethicone 6 (UNII: XHK3U310BA)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
phenoxyethanol (UNII: HIE492ZZ3T)	
polyoxyl 20 cetostearyl ether (UNII: YRC528SWUY)	
methylparaben (UNII: A218C7H9T)	
xanthan gum (UNII: TTV12P4NEE)	
mannitol (UNII: 3OWL53L36A)	
propylparaben (UNII: Z8IX2SC1OH)	
butylparaben (UNII: 3QPI1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
isobutylparaben (UNII: 0QQJ25X58G)	
arginine (UNII: 94ZLA3W45F)	
yeast (UNII: 3NY3SM6B8U)	
histidine monohydrochloride (UNII: 1D5Q932XM6)	
pea (UNII: W4X7H8GYFM)	
sodium succinate anhydrous (UNII: V8ZGC8ISR3)	
khaya senegalensis bark (UNII: 1S7EDA839L)	

nadide (UNII: 0U46U6E8UK)	
pyridoxine hydrochloride (UNII: 68Y4CF58BV)	
aspartic acid (UNII: 30KYC7MIAI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-304-02	1 in 1 BOX		
1	NDC:14783-304-01	50 mL in 1 BOTTLE		
2	NDC:14783-304-04	1 in 1 BOX		
2	NDC:14783-304-03	5 mL in 1 BOTTLE		
3	NDC:14783-304-05	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	04/19/2011	

Labeler - Ventura International Ltd. (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A.		880160197	MANUFACTURE

Revised: 2/2011

Ventura International Ltd.