

**LBEL PROTEGE EXPERT- octinoxate, octisalate, oxybenzone, and titanium dioxide lotion
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
PROTEGE
EXPERT
moisturizing body
protector lotion
SPF 15**

Drug Facts

Active Ingredients

Octinoxate 7.5%,
Octisalate 5%,
Oxybenzone 6%,
Titanium dioxide 2.34%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Provides moderate 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, methyl methacrylate crosspolymer, cyclopentasiloxane, dimethicone, cetearyl alcohol, sorbitan stearate, cyclohexasiloxane, glyceryl stearate, potassium cetyl phosphate, tocopheryl acetate, trimethylsiloxysilicate, phenoxyethanol, silica, 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), acetyl tyrosine, disodium succinate, khaya senegalensis bark extract, nicotinamide adenine dinucleotide, pyridoxine hci, aspartic acid

PRINCIPAL DISPLAY PANEL - 180 ml Bottle Carton

L'BEL

PROTÈGE
EXPERT

moisturizing body
protector lotion
SPF 15

WATER RESISTANT

180 ml e (6.3 fl.oz.)

UVB SPF

15

Moderate
Protection

UVA

PA ++



• HYPOALLERGENIC
• DERMATOLOGICALLY TESTED

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L'BEL

PROTÈGE EXPERT

moisturizing body
protector lotion
SPF 15

loción protectora
hidratante para cuerpo
FPS 15

WATER RESISTANT
RESISTENTE AL AGUA

180 ml e (6.3 fl.oz.)

UVA	UVA
15	PA ++
Moderate Protection	

octinoxate, octisalate, oxybenzone, and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-026
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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	.0234 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
dicaprylyl carbonate (UNII: 609A3V1SUA)	
alkyl (c12-15) benzoate (UNII: A9EJ3J61HQ)	
trolamine (UNII: 9O3K93S3TK)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
dimethicone (UNII: 92RU3N3Y1O)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
sorbitan monostearate (UNII: NVZ4I0H58X)	
cyclomethicone 6 (UNII: XHK3U310BA)	
glyceryl monostearate (UNII: 230OU9XXE4)	
potassium cetyl phosphate (UNII: 03KCY6P7UT)	
phenoxyethanol (UNII: HIE492ZZ3T)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
polyoxyl 20 cetostearyl ether (UNII: YRC528SWUY)	
methylparaben (UNII: A2I8C7HI9T)	
xanthan gum (UNII: TTV12P4NEE)	
mannitol (UNII: 3OWL53L36A)	
propylparaben (UNII: Z8IX2SC1OH)	
butylparaben (UNII: 3QPII03FV8)	
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: 30KYC7MIAD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-026-02	1 in 1 BOX		
1	NDC:13537-026-01	5 mL in 1 TUBE		
2	NDC:13537-026-04	1 in 1 BOX		
2	NDC:13537-026-03	10 mL in 1 TUBE		
3	NDC:13537-026-06	1 in 1 BOX		
3	NDC:13537-026-05	180 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	08/10/2011	

Labeler - Ventura Corporation Ltd. (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
BelStar, S.A.		880160197	MANUFACTURE

Revised: 8/2011

Ventura Corporation Ltd.