

LBEL PARIS REGRESSION JOUR- avobenzone, ensulizole, octinoxate, and oxybenzone cream

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 PARIS REGRESSION JOUR

Drug Facts

Active Ingredients

Avobenzone (2 %), Ensulizole (1 %), Octinoxate (7.5 %), Oxybenzone (2 %)

Purpose

Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection
- provides moderate protection against sunburn

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 and 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 smoothly every morning before sun exposure and as needed.
- apply after cleansing and toning on face and neck.
- children under 6 months of age: ask a doctor.

Other information

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

Inactive ingredients

Aqua (water), glycine soja (soybean) protein, propylene glycol, cyclopentasiloxane, cetyl alcohol, c12-15 alkyl benzoate, pisum sativum (pea) extract, cyclohexasiloxane, triethanolamine, glyceryl stearate, mannitol, corn starch modified, polyacrylamide, phenoxyethanol, stearic acid, hydrolyzed adansonia digitata extract, peg-75 stearate, methylparaben, c13-14 isoparaffin, propylparaben, xanthan gum, parfum (fragrance), ceteth-20, steareth-20, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, acrylates/c10-30 alkyl acrylate crosspolymer, disodium edta, laureth-7, cyclodextrin, dimethicone crosspolymer, faex extract (yeast extract), dimethicone, hydrolyzed algin, butylparaben, ethylparaben, chlorella vulgaris extract, maris aqua (sea water), isobutylparaben, laureth-23, laureth-4, disodium succinate, ci42090 (blue 1).

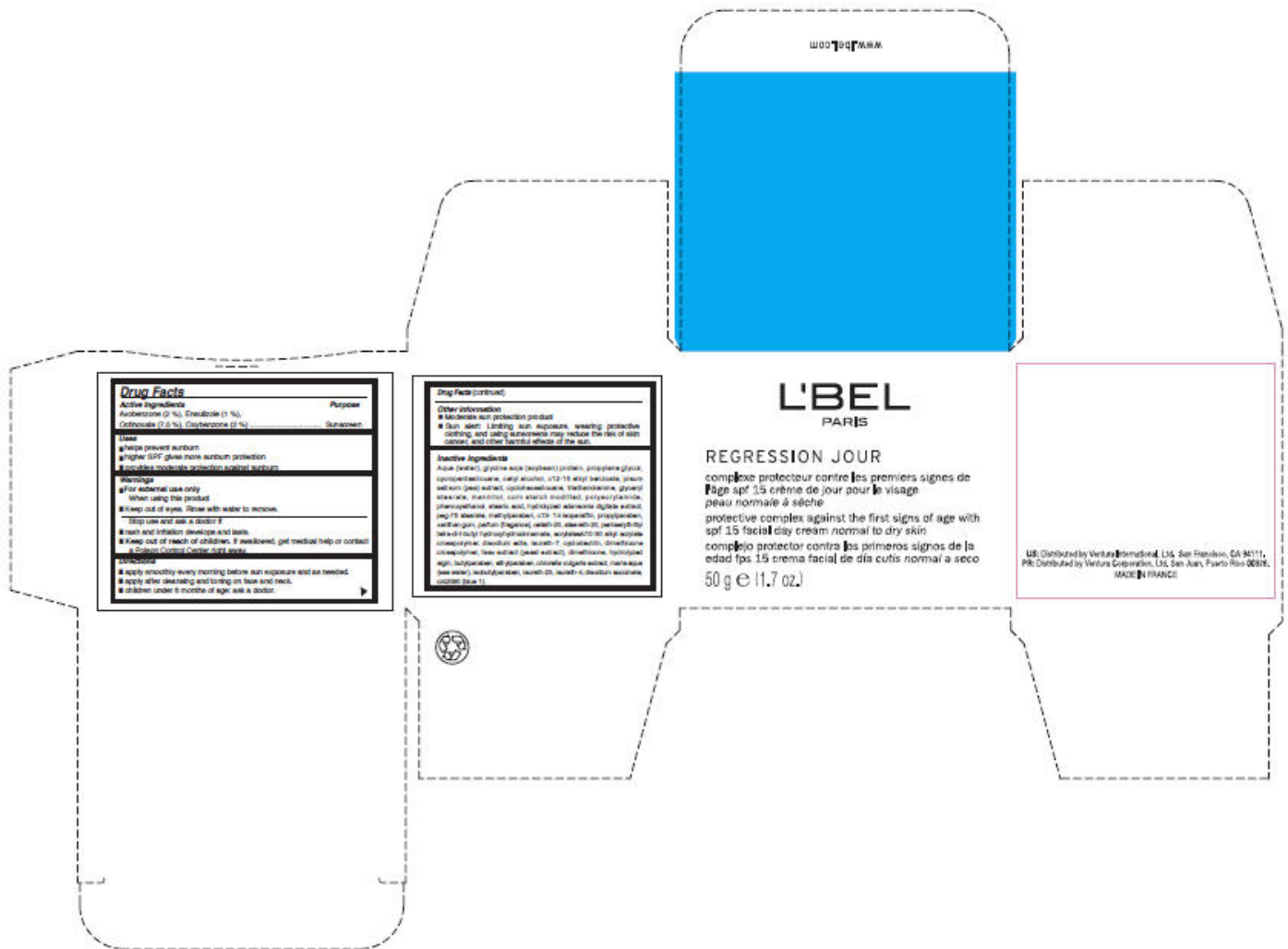
PRINCIPAL DISPLAY PANEL - 50 g Jar Carton

L'BEL
PARIS

REGRESSION JOUR

protective complex against the first signs of age with
spf 15 facial day cream *normal to dry skin*

50 g e (1.7 oz.)



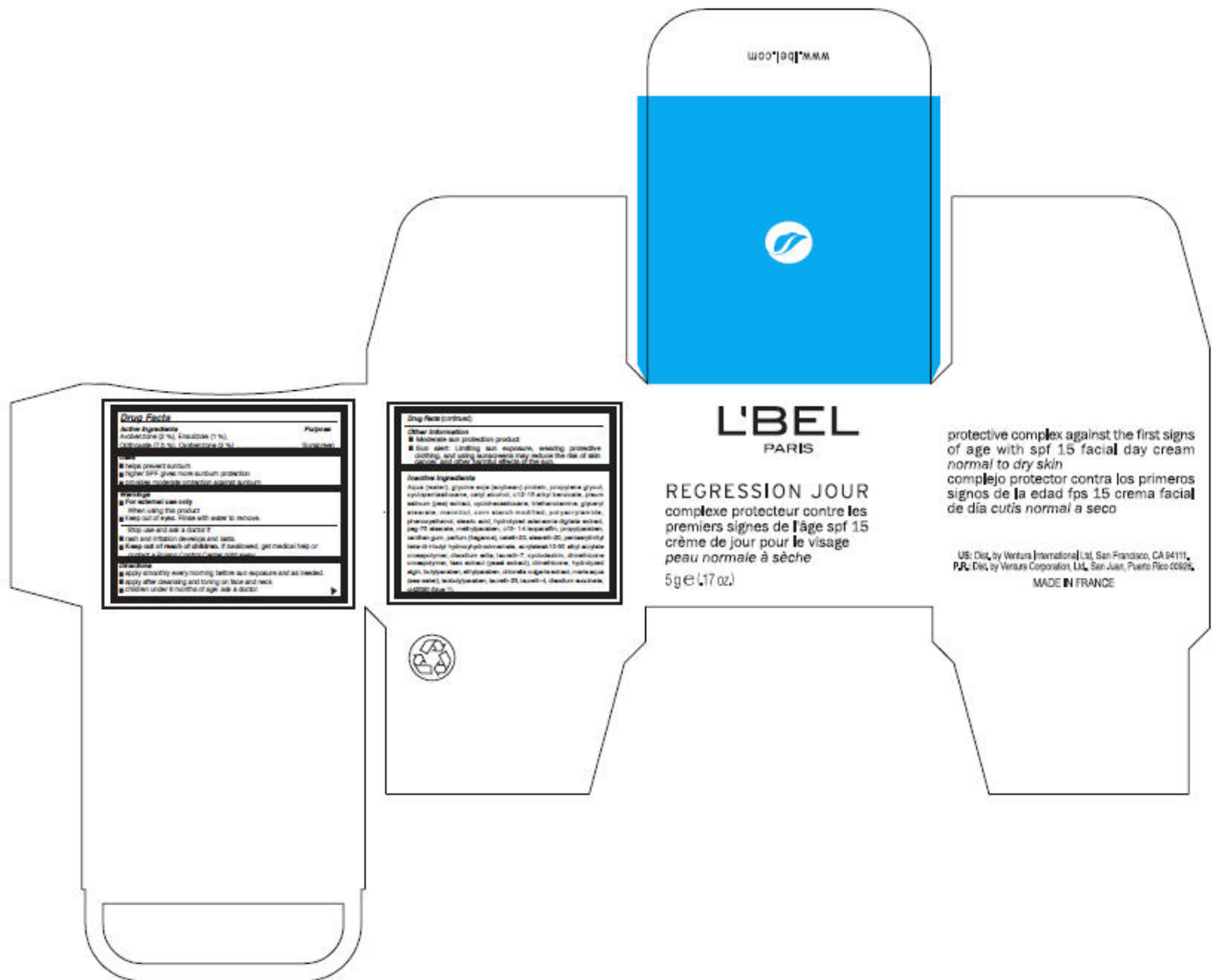
PRINCIPAL DISPLAY PANEL - 5 g Jar Carton

**L'BEL
PARIS**

REGRESSION JOUR

protective complex against the first signs
of age with spf 15 facial day cream
normal to dry skin

5 g e (.17 oz.)



LBEL PARIS REGRESSION JOUR

avobenzone, ensulizole, octinoxate, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-049
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzene (UNII: G63QQF2NOX) (Avobenzene - UNII:G63QQF2NOX)	Avobenzene	1 g in 50 g
Ensulizole (UNII: 9YQ9D11W42) (Ensulizole - UNII:9YQ9D11W42)	Ensulizole	0.5 g in 50 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	3.75 g in 50 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	1 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
soybean (UNII: L7HT8F1ZOD)	
propylene glycol (UNII: 6DC9Q167V3)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
cetyl alcohol (UNII: 936JST6JCN)	
c12-15 alkyl benzoate (UNII: A9EJ3J61HQ)	
snow pea (UNII: 84SKC33B1I)	
cyclomethicone 6 (UNII: XHK3U310BA)	
trolamine (UNII: 9O3K93S3TK)	
glyceryl monostearate (UNII: 230OU9XXE4)	
mannitol (UNII: 3OWL53L36A)	
phenoxyethanol (UNII: HIE492ZZ3T)	
stearic acid (UNII: 4ELV7Z65AP)	
methylparaben (UNII: A2I8C7HI9T)	
c13-14 isoparaffin (UNII: E4F12ROE70)	
propylparaben (UNII: Z8IX2SC1OH)	
xanthan gum (UNII: TTV12P4NEE)	
ceteth-20 (UNII: I835H2IHHX)	
steareth-20 (UNII: L0Q8IK9E08)	
edetate disodium (UNII: 7FLD91C86K)	
laureth-7 (UNII: Z95S6G8201)	
yeast (UNII: 3NY3SM6B8U)	
dimethicone (UNII: 92RU3N3Y1O)	
butylparaben (UNII: 3QPH1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
isobutylparaben (UNII: 0QQJ25X58G)	
laureth-23 (UNII: N72LMW566G)	
laureth-4 (UNII: 6HQ855798J)	
sodium succinate anhydrous (UNII: V8ZGC8ISR3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-049-61	1 in 1 BOX		
1	NDC:14783-049-62	50 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/15/2010	

LBEL PARIS REGRESSION JOUR

avobenzone, ensulizole, octinoxate, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-039
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.1 g in 5 g
Ensulizole (UNII: 9YQ9D11W42) (Ensulizole - UNII:9YQ9D11W42)	Ensulizole	0.05 g in 5 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.375 g in 5 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.1 g in 5 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
soybean (UNII: L7HT8F1ZOD)	
propylene glycol (UNII: 6DC9Q167V3)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
cetyl alcohol (UNII: 936JST6JCN)	
c12-15 alkyl benzoate (UNII: A9EJ3J61HQ)	
snow pea (UNII: 84SKC33B1I)	
cyclomethicone 6 (UNII: XHK3U310BA)	
trolamine (UNII: 9O3K93S3TK)	
glyceryl monostearate (UNII: 230OU9XXE4)	
mannitol (UNII: 3OWL53L36A)	
phenoxyethanol (UNII: HIE492ZZ3T)	
stearic acid (UNII: 4ELV7Z65AP)	
methylparaben (UNII: A218C7H9T)	
c13-14 isoparaffin (UNII: E4F12ROE70)	
propylparaben (UNII: Z8IX2SC1OH)	
xanthan gum (UNII: TTV12P4NEE)	
ceteth-20 (UNII: I835H2IHHX)	
steareth-20 (UNII: L0Q8IK9E08)	
edetate disodium (UNII: 7FLD91C86K)	
laureth-7 (UNII: Z95S6G8201)	
yeast (UNII: 3NY3SM6B8U)	
dimethicone (UNII: 92RU3N3Y1O)	
butylparaben (UNII: 3QPIU3FV8)	
ethylparaben (UNII: 14255EXE39)	

isobutylparaben (UNII: 0QQJ25X58G)	
laureth-23 (UNII: N72LMW566G)	
laureth-4 (UNII: 6HQ855798J)	
sodium succinate anhydrous (UNII: V8ZGC8ISR3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-039-51	1 in 1 BOX		
1	NDC:14783-039-52	5 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/15/2010	

Labeler - Ventura International LTD (603192787)

Revised: 8/2010

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