

LBEL EFFET PARFAIT LOOSE EXTRA-FINE PORTABLE- titanium dioxide, oxybenzone, and octinoxate powder

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

EFFET PARFAIT loose extra-fine portable powder SPF 15

Drug Facts

<i>Active Ingredient</i>	<i>Purpose</i>
Titanium Dioxide 3.5%	Sunscreen
Oxybenzone 3.0 %	Sunscreen
Octinoxate 3.0%	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 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 generously and evenly before sun exposure and as needed

Inactive ingredients

Talc, Zea Mays Starch(Zea Mays (Corn) Starch), Titanium Dioxide, Silica, Benzophenone-3, Calcium Carbonate, Ethylhexyl Methoxycinnamate, Kaolin, Zinc Stearate, Octyldodecanol, Isostearyl Neopentanoate, Glyceryl Caprylate, Methyl Methacrylate Crosspolymer, Magnesium Myristate, Hydrogen Dimethicone, Tocopheryl Acetate, Methylparaben, Propylparaben, Alumina, Microcristallina Cera (Microcrystalline Wax), Petrolatum, Phospholipids, Cholesterol, Candelilla Cera (Euphorbia Cerifera (Candelilla Wax), Cera Alba (Beeswax), Cetearyl Alcohol, Cetearyl Glucoside, Copernicia Cerifera Cera (Copernicia Cerifera (Carnauba) Wax), Polyglyceryl-2 Dipolyhydroxystearate, Glycosphingolipids. **May Contain:** CI 77499, CI 77492, CI 77491 (Iron Oxides), CI 77891 (Titanium Dioxide).

Dist. by Ventura International Ltd. San Francisco, CA 94111.

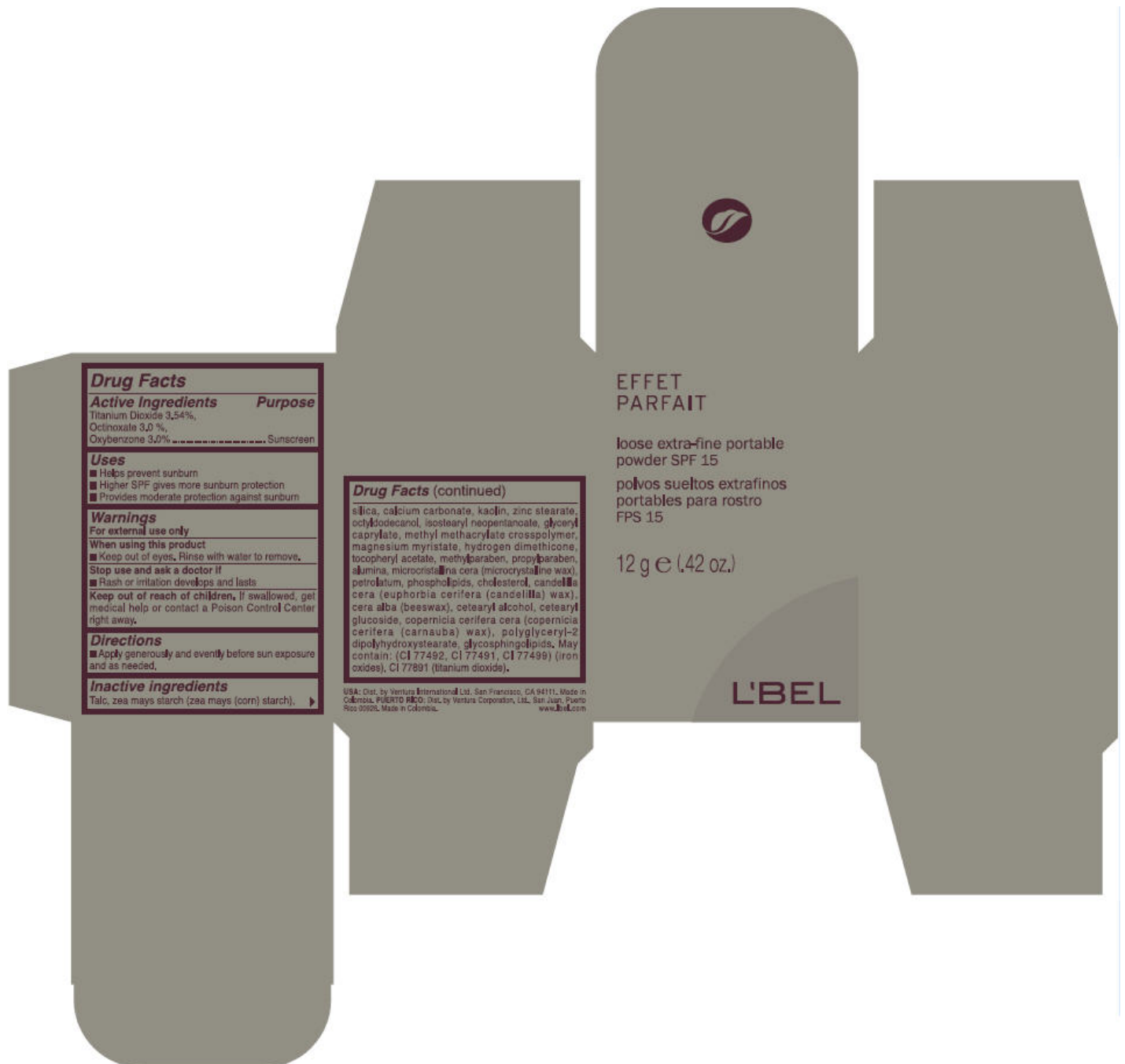
PRINCIPAL DISPLAY PANEL - 12 g Bottle Carton

EFFET
PARFAIT

loose extra-fine portable
powder SPF 15

12 g e (.42 oz.)

L'BEL



LBEL EFFET PARFAIT LOOSE EXTRA-FINE PORTABLE

titanium dioxide, oxybenzone, and octinoxate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-448
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.035 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.03 g in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
KAOLIN (UNII: 24H4NWX5CO)	
ZINC STEARATE (UNII: H92E6QA4FV)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
MAGNESIUM MYRISTATE (UNII: Z1917F0578)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALUMINUM OXIDE (UNII: LM26O6933)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-448-02	1 in 1 BOX		
1	NDC:14783-448-01	12 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/24/2012	

Labeler - Ventura International Ltd (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-448)

Revised: 1/2012

Ventura International Ltd