

LBEL EFFET PARFAIT MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10- zinc oxide 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 Effet Parfait maximum comfort and long-lasting foundation spf 10

Drug Facts

Active Ingredients

Zinc oxide 1.57 %

Purpose

sunscreen

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Provides minimal 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 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.
- Apply to the forehead, nose, chin and both cheeks. Blend with circular motion and spread softly without stretching the skin.

Inactive ingredients

water, cyclopentasiloxane, cyclomethicone, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone, cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg 18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, CI 77163 (bismuth oxychloride), silica silylate, CI 77019 (mica), trimethylsiloxysilicate, methylparaben, triethoxycaprylylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, parfum (fragrance),

butylparaben, ethylparaben, silica, isobutylparaben. May contain: ci 77891 (titanium dioxide), CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77499(iron oxides).

PUERTO RICO: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Columbia

PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton

**EFFET
PARFAIT**

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and long-lasting
foundation
SPF 10

30 ml e (1 fl.oz.)

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Drug Facts (continued)

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■ Apply to the forehead, nose, chin and both cheeks. Blend with circular motion and spread softly without stretching the skin.

Inactive ingredients

Aqua (water), cyclopentasiloxane, cyclomethicone, dimethicone, polymethyl methacrylate, peg/ppg-18/18 dimethicone.

Drug Facts (continued)

cyclohexasiloxane, methyl methacrylate crosspolymer, sodium chloride, bis-hydroxyethoxypropyl dimethicone, bis-peg 18 methyl ether dimethyl silane, peg/ppg-19/19 dimethicone, glycerin, oleth-5, phenyl trimethicone, hydrolyzed soy protein, propylene glycol, CI 77163 (bismuth oxychloride), silica silylate, CI 77019 (mica), trimethylsilyloxyoctyl dimethylsilane, triethoxycaprylsilane, propylparaben, tocopheryl acetate, phenoxyethanol, parfum (fragrance), butylparaben, ethylparaben, silica, isobutylparaben. May contain: CI 77891 (titanium dioxide), CI 77492 (iron oxides), CI 77491 (iron oxides), CI 77499 (iron oxides).

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SPF 10

30 ml e (1 fl.oz.)

L'BEL

USA: Distributed by Ventura International, Ltd, San Francisco, CA 94111, Made in Colombia. **PUERTO RICO:** Distributed by Ventura Corporation, Ltd, San Juan, Puerto Rico 00926. Made in Colombia. www.lbel.com

LBEL EFFET PARFAIT MAXIMUM COMFORT AND LONG-LASTING FOUNDATION SPF 10

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-428
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.0157 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG/PPG-19/19 DIMETHICONE (UNII: EHH90CO7TL)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLETH-5 (UNII: 1GH33785AY)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
MICA (UNII: V8A1AW0880)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
TRIETHOXYCAPRYL SILANE (UNII: LDC331P08E)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYL PARABEN (UNII: 3QP1I3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-428-02	1 in 1 BOX		

1	NDC:13537-428-01	30 mL in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352		02/10/2012	

Labeler - Ventura Corporation Ltd. (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Belstar (Colombia)		880160197	MANUFACTURE(13537-428)

Revised: 3/2012

Ventura Corporation Ltd.