

LBEL SUPREMACIE TEINT- octinoxate 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
SUPRÉMACIE TEINT

Drug Facts

Active Ingredients

Octinoxate (4.5 %)

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

- moderate sun protection product
- apply smoothly every morning before sun exposure and as needed.
- children under 6 months of age: ask a doctor.

Other information

- 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), cyclopentasiloxane, butylene glycol, cyclohexasiloxane, phenyl trimethicone, polyglyceryl-4 isostearate, cetyl peg/ppg-10/1 dimethicone, polydodecanamideaminium triazadiphenylethanesulfonate, hexyl laurate, mannitol, glycerin, peg/ppg-18/18 dimethicone, glycine

soja (soybean) protein, ethylene/acrylic acid copolymer, sodium chloride, disteardimonium hectorite, dimethicone, propylene glycol, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, diazolidinyl urea, hydrolyzed keratin, dimethiconol, sucrose, methylparaben, serine, parfum (fragrance), methicone, arginine, cyclodextrin, polyvinylalcohol crosspolymer, pca, bht, macrocystis pyrifera extract, faex extract (yeast extract), alanine, propylparaben, hydrolyzed wheat protein, pvp, carbomer, polysorbate 20, disodium succinate, palmitoyl pentapeptide-4, threonine, mourera fluviatilis extract. **May contain:** ci 77891(titanium dioxide), ci 77491, ci 77492, ci 77499 (iron oxides).

US: Distributed by Ventura International, Ltd. San Francisco, CA 94111

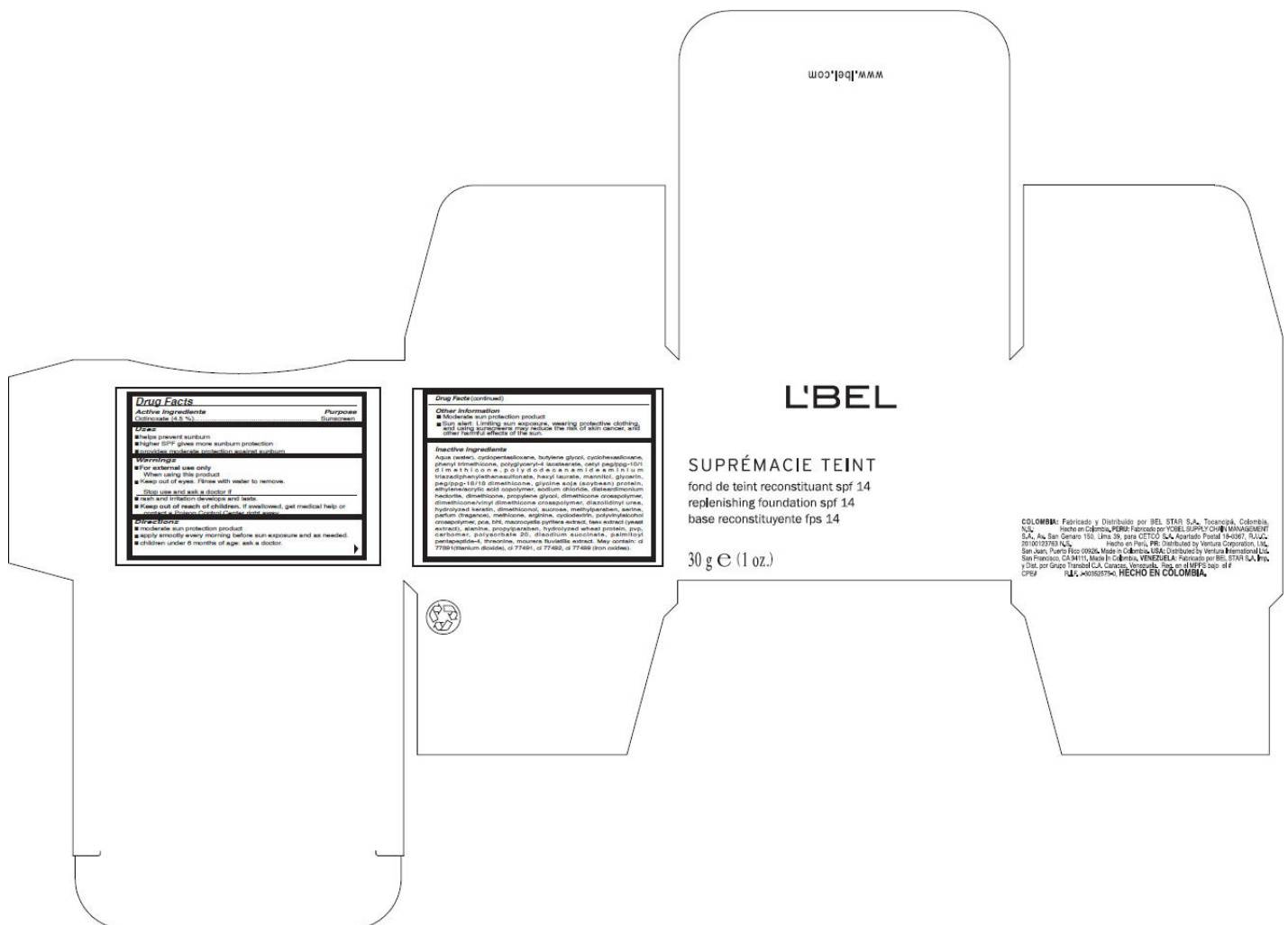
PRINCIPAL DISPLAY PANEL - 30 g Carton

L'BEL

SUPRÉMACIE TEINT

replenishing foundation spf 14

30 g e (1 oz.)



LBEL SUPREMACIE TEINT

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-085
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	1.35 g in 30 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
butylene glycol (UNII: 3XUS85K0RA)	
cyclomethicone 6 (UNII: XHK3U310BA)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
polyglyceryl-4 isostearate (UNII: 820DPX33S7)	
dimethicone (UNII: 92RU3N3Y1O)	
hexyl laurate (UNII: 4CG9F9W01Q)	
mannitol (UNII: 3OWL53L36A)	
glycerin (UNII: PDC6A3C0OX)	
glycine (UNII: TE7660XO1C)	
sodium chloride (UNII: 451W47IQ8X)	
hectorite (UNII: 08X4KI73EZ)	
propylene glycol (UNII: 6DC9Q167V3)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	
sucrose (UNII: C151H8M554)	
methylparaben (UNII: A2I8C7HI9T)	
serine (UNII: 452VLY9402)	
arginine (UNII: 94ZLA3W45F)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
yeast (UNII: 3NY3SM6B8U)	
alanine (UNII: OF5P57N2ZX)	
propylparaben (UNII: Z8IX2SC1OH)	
wheat (UNII: 4J2I0SN84Y)	
polysorbate 20 (UNII: 7T1F30V5YH)	
sodium succinate anhydrous (UNII: V8ZGC8ISR3)	
threonine (UNII: 2ZD004190S)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferrosoferric oxide (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-085-63	1 in 1 BOX		

1	NDC:14783-085-64	30 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)

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VENTURA INTERNATIONAL LTD.,