

LBEL COULEUR LUXE AMPLIFIER XP AMPLIFYING SPF 15- octinoxate and oxybenzone lipstick

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.

**COULER LUXE AMPLIFIER XP
amplifying lipstick**

Drug Facts

Active Ingredients

Octinoxate 4.7 %, Oxybenzone 0.9%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- Skin Cancer / Skin Aging Alert; Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
- For external use only.
- Do not use on damage or broken skin.
- When using this product keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash occurs.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Children under 6 months of age: Ask a doctor.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Apply lipstick following the curves of natural lip line. For added definition, use with a lip pencil.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

isostearyl neopentanoate, diisopropyl dimer dilinoleate, methyl hydrogenated rosinat, mica, polyethylene, castor isostearate beeswax succinate, ethylhexyl methoxycinnamate, hydrogenated polycyclopentadiene, silica, copernicia cerifera (carnauba) wax, euphorbia cerifera (candelilla) wax, ozokerite, ethylhexyl palmitate, isododecane, hydrogenated polyisobutene, paraffin, polyglyceryl-3 diisostearate, glyceryl isostearate, isostearyl alcohol, dipalmitoyl hydroxyproline, benzophenone-3, ceramide 3, butyrospermum parkii (shea) butter, beta-sitosterol, dimethicone, propylparaben, luffa cylindrica seed oil, silica silylate, methylparaben, disteardimonium hectorite, fragrance, peg-40 hydrogenated castor oil, polysorbate 80, ppg-26-buteth-26, bht, trimethylsiloxysilicate, heder helix (ivy) leaf/stem extract, retinyl palmitate, tocopheryl acetate, bioflavonoids, allantoin, ascorbyl palmitate.

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PRINCIPAL DISPLAY PANEL - 4 g Tube Carton

COULEUR LUXE AMPLIFIER XP

amplifying lipstick

SPF 15

4 g e (.14 oz.)

L'BEL

Drug Facts (continued)

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US: Distributed by Ventura International Ltd. DBA Belcorp USA, San Francisco, CA 94111 P.R.: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Colombia. www.lbel.com

COULEUR LUXE AMPLIFIER XP

amplifying lipstick
SPF 15

4 g e (1.4 oz.)

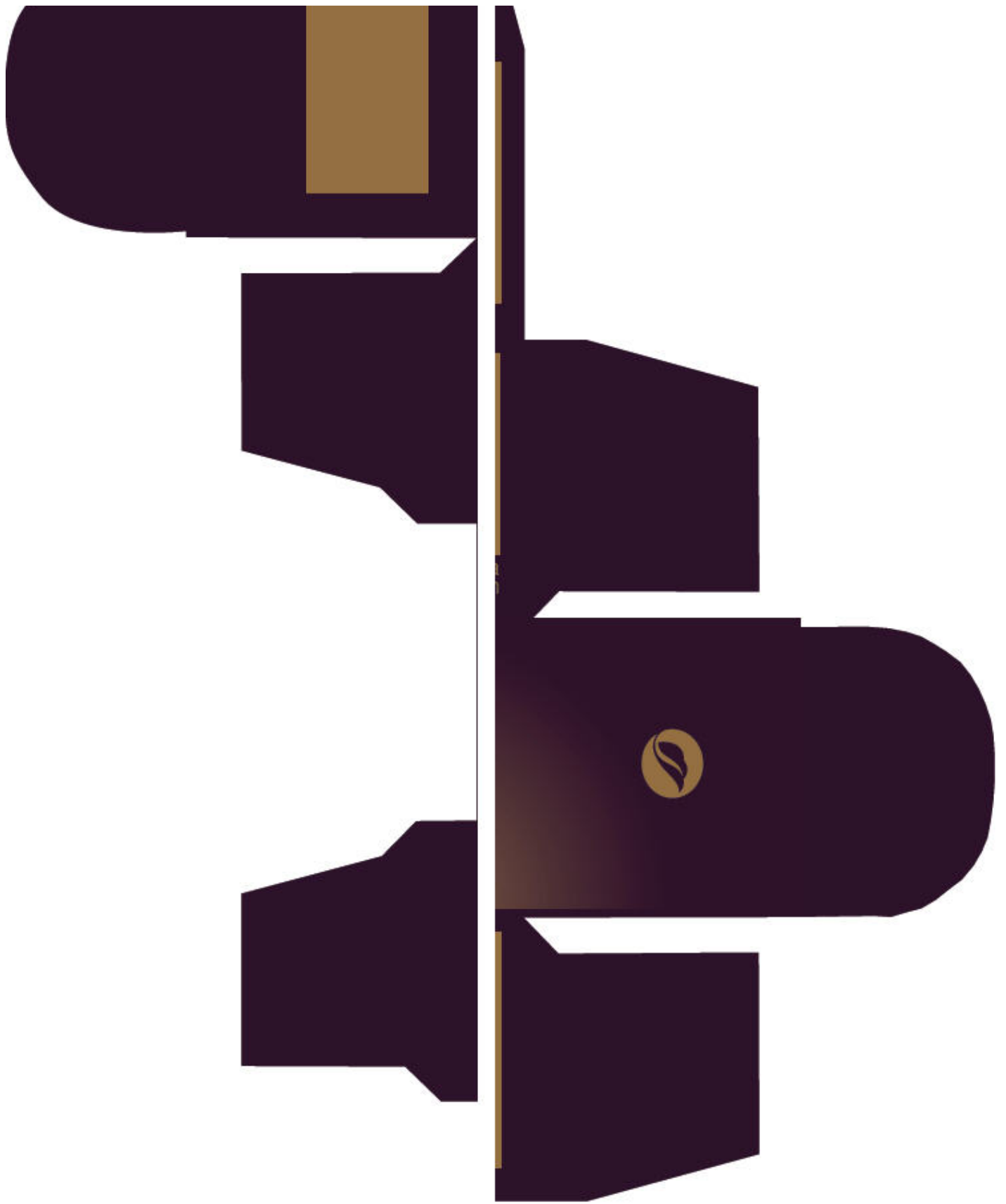
L'BEL

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.047 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.009 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
isostearyl neopentanoate (UNII: 411THY156Q)	
diisopropyl dilinoleate (UNII: 5323S7S2LR)	
mica (UNII: V8A1AW0880)	
high density polyethylene (UNII: UG00KM4WR7)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
carnauba wax (UNII: R12CBM0EIZ)	
candelilla wax (UNII: WL0328HX19)	
ethylhexyl palmitate (UNII: 2865993309)	
isododecane (UNII: A8289P68Y2)	
paraffin (UNII: I9O0E3H2ZE)	
polyglyceryl-3 diisostearate (UNII: 46P231IQV8)	
glyceryl isostearate (UNII: HYE7O27HAO)	
isostearyl alcohol (UNII: Q613OCQ44Y)	
dipalmitoyl hydroxyproline (UNII: E6AHA53N1H)	
ceramide 3 (UNII: 4370DF050B)	
shea butter (UNII: K49155WL9Y)	
.beta.-sitosterol (UNII: S347WMO6M4)	
dimethicone (UNII: 92RU3N3Y1O)	
propylparaben (UNII: Z8IX2SC1OH)	
luffa aegyptiaca seed oil (UNII: 1A281RJ859)	
methylparaben (UNII: A218C7HI9T)	
polyoxyl 40 hydrogenated castor oil (UNII: 7YC686GQ8F)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
ppg-26-buteth-26 (UNII: 2II1K6TZ4P)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
hedera helix leaf (UNII: ZP9XFG71A7)	
vitamin a palmitate (UNII: 1D1K0N0VVC)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
citrus bioflavonoids (UNII: BD70459I50)	
allantoin (UNII: 344S277G0Z)	
ascorbyl palmitate (UNII: QN83US2B0N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-012-02	1 in 1 BOX		

1	NDC:14783-012-01	4 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part352	09/14/2012		

Labeler - Ventura International LTD. (603192787)

Establishment			
Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-012)

Revised: 8/2012

Ventura International LTD.