

**LBEL HYDRA CALME SPF 15- octinoxate, octisalate, and oxybenzone lotion**  
**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.*

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**L'BEL**  
**HYDRA CALME**

***Drug Facts***

<b><i>Active Ingredient</i></b>	<b><i>Purpose</i></b>
Octinoxate 7.5%	Sunscreen
Octisalate 4.0 %	Sunscreen
Oxybenzone 4.0%,	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 smoothly every morning before sun exposure and as needed.
- Use in the morning after cleansing and toning. Apply small amounts using the fingertips and spreading with upward, circular movements. Rub gently until absorbed completely.
- Children under 6 months of age: ask a doctor.
- Moderate sun protection product

**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.

**Inactive ingredients**

aqua (water), c12-15 alkyl benzoate, pisum sativum extract (pisum sativum (pea) extract), cyclohexasiloxane, dimethicone, butylene glycol, cetearyl alcohol, erythritol, hdi/trimethylol hexyllactone crosspolymer, phenoxyethanol, sodium acrylate/ acryloyldimethyltaurate/

dimethylacrylamide crosspolymer, c20-22 alkyl phosphate, glyceryl stearate, hydroxyethyl acrylate/  
sodium acryloyldimethyl taurate copolymer, propylene glycol, c20-22 alcohols, triethanolamine,  
isohexadecane, methylparaben, parfum (fragrance), c14-22 alcohols, cetearyl glucoside, butylparaben,  
cyclopentasiloxane, chlorphenesin, xanthan gum, propylparaben, acrylates/ c10-30 alkyl acrylate  
crosspolymer, disodium edta, sorbic acid, polysorbate 60, c12-20 alkyl glucoside, glycerin,  
hydrolyzed algin, ethylparaben, chlorella vulgaris extract, maris aqua (sea water), isobutylparaben,  
silica, homarine hcl, rubus chamaemorus fruit extract

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

**PRINCIPAL DISPLAY PANEL - 50 ml Bottle Carton**

**L'BEL**

HYDRA CALME

**SPF 15**

intensive moisturizing  
face lotion with SPF 15

50 ml e (1.6 fl.oz.)

www.lbel.com

L'BEL

To help protect the skin against dehydration, tightness, roughness, dullness and loss of vitality, L'Bel presents the Hydra Calme Intensive Moisturizing Line. A miracle of maximum moisturization and comfort for all ages and skin types.

A new skin care concept whose extraordinary revitalizing and comforting action inundates the skin with a pleasant feeling of freshness, softness and well-being to protect it and recover its appearance of beauty and youthfulness.

**Drug Facts (continued)**

**Directions**

- Apply smooth every morning before sun exposure and as needed.
- Use in the morning after cleansing and toning. Apply small amounts using the fingertips and spreading with upward, circular movements. Rub gently until absorbed completely.
- Children under 6 months of age: ask a doctor.
- Moderate sun protection product.

**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), c12-15 alkyl benzoate, pisum sativum extract (pisum sativum (pea) extract), cyclohexasiloxane, dimethicone, butylene glycol, cetearyl alcohol, erythritol, hdi/trimethylol hexylactone copolymer, phenoxyethanol, sodium acrylate/ acryloyldimethyl taurate/ dimethylacrylamide copolymer, c20-22 alkyl phosphate, glyceryl stearate, hydroxyethyl acrylate/ sodium acryloyldimethyl taurate copolymer, propylene glycol, c20-22 alcohols, triethanolamine, isohexadecane.

**Drug Facts (continued)**

methylparaben, parfum (fragrance), c14-22 alcohols, cetearyl glucoside, butylparaben, cyclopentasiloxane, chlorphenesin, xanthan gum, propylparaben, acrylates/ c10-30 alkyl acrylate copolymer, disodium edta, sorbic acid, polysorbate 60, c12-20 alkyl glucoside, glycerin, hydrolyzed algin, ethylparaben, chloroform extract, maris aqua (sea water), isobutylparaben, silica, homarine hcl, rubus chamaemorus fruit extract.

US: Dist. by Venture International Ltd, San Francisco, CA 94111. Made in Colombia P.R.: Dist by Ventura Corporation, Ltd, San Juan, Puerto Rico 00925. Made in Colombia, CO: Fab, y dist, por BEL STAR S.A., Tocanipá, Colombia, N.S. Hecho en Colombia, PE: Fab, y dist, por YOSSEL SUPPLY CHAIN MANAGEMENT S.A, Av. San Gerardo 150, Lima 39, para CETCO S.A. Aterizado Postal 18-0867, P.V.M.C. 20100123783 N.S. Hecho en Perú.

HYDRA CALME

SPF 15

intensive moisturizing face lotion with SPF 15

loción hidratante intensiva para el rostro con FPS 15

50 ml e (1.6 fl.oz.)

**Drug Facts**

**Active Ingredients Purpose**

Octinoxate (7.5%), Octisalate (4%), Oxybenzone (4%), ..... 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.

# LBEL HYDRA CALME SPF 15

octinoxate, octisalate, and oxybenzone lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14783-400
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.04 g in 1 mL
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.04 g in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>water</b> (UNII: 059QF0KO0R)	
<b>alkyl (c12-15) benzoate</b> (UNII: A9EJ3J61HQ)	
<b>pea</b> (UNII: W4X7H8GYFM)	
<b>cyclomethicone 6</b> (UNII: XHK3U310BA)	
<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>butylene glycol</b> (UNII: 3XUS85K0RA)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>erythritol</b> (UNII: RA96B954X6)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>c20-22 alkyl phosphate</b> (UNII: L4VKP0Y7RP)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>c20-22 alcohols</b> (UNII: O4M0347C6A)	
<b>trolamine</b> (UNII: 9O3K93S3TK)	
<b>isohexadecane</b> (UNII: 918X10UF1E)	
<b>methylparaben</b> (UNII: A218C7HI9T)	
<b>c14-22 alcohols</b> (UNII: B1K89384RJ)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>butylparaben</b> (UNII: 3QPHU3FV8)	
<b>cyclomethicone 5</b> (UNII: 0THT5PCI0R)	
<b>chlorphenesin</b> (UNII: I670DAL4SZ)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>edetate disodium</b> (UNII: 7FLD91C86K)	
<b>sorbic acid</b> (UNII: X045WJ989B)	
<b>polysorbate 60</b> (UNII: CAL22UVI4M)	
<b>c12-20 alkyl glucoside</b> (UNII: K67N5Z1RUA)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>ethylparaben</b> (UNII: 14255EXE39)	
<b>chlorella vulgaris</b> (UNII: RYQ4R60M02)	
<b>isobutylparaben</b> (UNII: 0QQJ25X58G)	

silicon dioxide (UNII: ETJ7Z6XBU4)

rubus chamaemorus fruit (UNII: 74CW8G72Q6)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-400-02	1 in 1 BOX		
1	NDC:14783-400-01	50 mL in 1 TUBE		
2	NDC:14783-400-04	1 in 1 BOX		
2	NDC:14783-400-03	5 mL in 1 TUBE		
3	NDC:14783-400-05	1 mL in 1 PACKET		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	09/01/2011	

**Labeler** - Ventura International Ltd. (603192787)

### Establishment

Name	Address	ID/FEI	Business Operations
Bel Star, S.A.		880160197	MANUFACTURE

### Establishment

Name	Address	ID/FEI	Business Operations
Yobel Supply Chain Management S.A.		934116930	MANUFACTURE

Revised: 9/2011

Ventura International Ltd.