

**LBEL HYDRA CALME SPF 15 INTENSIVE MOISTURIZING FACIAL - octinoxate, octisalate, 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 SPF 15 Intensive Moisturizing Facial Lotion**

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**Active Ingredients**

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

**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 damaged 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**

- 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.
- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor.

## **Other information**

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 / acryloyldimethyl-taurate / 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/c10-20 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.

## **Purpose**

Sunscreen

## **EXPERT ROUTINE L'BEL**

L'Bel presents Expert Routine, a skin care program with two steps that work together for enhanced results:

1. Cleanse the skin according to its needs
2. Nourish according to the age.

## **HYDRA CALME**

Intensive moisturizing line

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 wellbeing to protect it and recover its appearance of beauty and youthfulness.

## **The fountain of youth the skin needs every day**

Hydra Calm Intensive Moisturizing Line offers immediate and prolonged moisturization to the areas of the face that need it most. Its exclusive formulas reestablish the skin's hydric balance and facilitate the transportation of water according to the skin's moisturization needs.

## **A discover that changed the concept of moisturization**

An innovative discovery in the world of cosmetic technology: **Hydra Comfort Systeme**. A powerful moisturizing complex based on Arctic Berry Extract, an exceptional source of carbohydrates, vitamins, minerals and antioxidants with comforting and softening properties.

**Two formulas for all ages and skin types**, both with a soft, comforting texture and rapid absorption properties:

### **1. Intensive moisturizing facial lotion SPF 15**

**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:** Apply smoothly every morning before sun exposure and as needed. Use in the morning after cleansing and toning. Apply small amounts using 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.
- HYPOALLERGENIC
- DERMATOLOGICALLY TESTED

**2. Intensive moisturizing facial cream gel**

**USE:** Use in the morning and / or at night after cleansing and toning. Apply small amounts using the fingertips and spreading with upward, circular movements. Rub gently until absorbed completely.

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- DERMATOLOGICALLY TESTED

L'BEL HYDRA CALME FPS 15 intensive moisturizing facial lotion SPF 15 50 ml e (1.6 fl.oz.)

US: Dist. by Ventural Internationa Ltd. DBA Bellcorp USA, San Francisco, CA 94111

P.R. Dist. by Ventura Corporation Ltd., San Juan, Puerto Rico 00926 MADE IN FRANCE

**L'BEL HYDRA CALME SPF 15 Intensive Moisturizing Facial Lotion**



# L'BEL

**ACTIVE INGREDIENTS:**

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

**USES:** Helps prevent sunburn.

**WARNINGS: Skin Cancer / Skin Aging**

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MADE IN FRANCE

## HYDRA CALME

### FPS 15

intensive moisturizing  
facial lotion SPF 15

50 ml e (1.6 fl.oz.)



# L'BEL

## HYDRA CALME

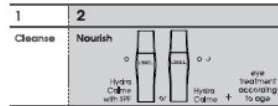
intensive moisturizing line

www.lbel.com

### EXPERT ROUTINE L'BEL

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MADE IN FRANCE

### Drug Facts (continued)

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### Directions

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- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

### Other information

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

### Drug Facts (continued)

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 alginate, ethylparaben, chlorella vulgaris extract, maris aqua (sea water), isobutylparaben, silica, homarine hcl, rubus chamaemorus fruit extract.

US: Distributed by Venture International, LLC, USA (Seppco USA, San Francisco, CA 94111), PUERTO RICO: Distributed by Venture Corporation, LUL, San Juan, Puerto Rico 00924.  
**MADE IN FRANCE**

# L'BEL

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### Drug Facts

#### Active Ingredients Purpose

Octinoxate (7.5%),  
Octisalate (4%),  
Oxybenzone (4 %),  
..... 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.
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## HYDRA CALME

### FPS 15

intensive moisturizing facial lotion SPF 15

50 ml e (1.6 fl.oz.)

# LBEL HYDRA CALME SPF 15 INTENSIVE MOISTURIZING FACIAL

octinoxate, octisalate, oxybenzone lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43455-0002
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 mL in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<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>SODIUM ACRYLATE</b> (UNII: 7C98FKB43H)	
<b>C20-22 ALKYL PHOSPHATE</b> (UNII: L4VKP0Y7RP)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>SODIUM ACRYLATE/SODIUM ACRYLO YLDIMETHYLTAURATE COPOLYMER (400000 MW)</b> (UNII: 1DXE3F3OZX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>C20-22 ALCOHOLS</b> (UNII: O4M0347C6A)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>C14-22 ALCOHOLS</b> (UNII: B1K89384RJ)	
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)	
<b>BUTYL PARABEN</b> (UNII: 3QPIIU3FV8)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PC10R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC10H)	
<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>ETHYL PARABEN</b> (UNII: 14255EXE39)	
<b>CHLORELLA VULGARIS</b> (UNII: RYQ4R60M02)	

ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HOMARINE HYDROCHLORIDE (UNII: 8866LNG61N)	
RUBUS CHAMAEMORUS FRUIT (UNII: 74CW8G72Q6)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43455-0002-0	1 mL in 1 POUCH		
2	NDC:43455-0002-1	3 mL in 1 TUBE		
3	NDC:43455-0002-2	30 mL in 1 JAR		
4	NDC:43455-0002-3	50 mL in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/25/2012	

**Labeler** - Ventura International, LTD (603192787)

### Establishment

Name	Address	ID/FEI	Business Operations
MF Productions		266769145	manufacture

Revised: 3/2012

Ventura International, LTD