LBEL REGRESSION JOUR PROTECTIVE COMPLEX WITH SPF 15 FACIAL DAY NORMAL TO COMBINATION SKIN - octinoxate, octis alate, oxybenzone 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 REGRESSION JOUR Protective Complex With SPF 15 Facial Day Lotion Normal to Combination Skin

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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

- Apply liberally and evenly 15 minutes before sun exposure.
- Apply after cleansing and toning on face and neck
- 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.
- Apply in the morning at the end of your skin care routine.
- Apply with the fingertips, spreading softly throughout the face until completely absorbed

Inactive Ingredients

AQUA (WATER), GLYCINE SOJA PROTEIN (GLYCINE SOJA (SOYBEAN) PROTEIN), C12-15 ALKYL BENZOATE, PISUM SATIVUM EXTRACT (PISUM SATIVUM (PEA) EXTRACT), CYCLOHEXASILOXANE, DIMETHICONE, MANNITOL, CETEARYL ALCOHOL, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, PHENOXYETHANOL, SODIUM ACRYLATE/ACRYLOYLDIMETHYLTAURATE/DIMETHYLACRYLAMIDE CROSSPOLYMER, C20-22 ALKYL PHOSPHATE, GLYCERYL STEARATE, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDYMETHYL TAURATE COPOLYMER, C20-22 ALCOHOLS, TRIETHANOLAMINE, ISOHEXADECANE, METHYLPARABEN, C14-22 ALCOHOLS, CETEARYL GLUCOSIDE, HYDROLYZED ADANSONIA DIGITATA EXTRACT, BUTYLPARABEN, CYCLOPENTASILOXANE, CHLORPHENESIN, XANTHAN GUM, PROPYLPARABEN, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, DISODIUM EDTA, PARFUM (FRAGRANCE), SORBIC ACID, POLYSORBATE 60, CYCLODEXTRIN, C12-20 ALKYL GLUCOSIDE, FAEX EXTRACT (YEAST EXTRACT), HYDROLYZED ALGIN, ETHYLPARABEN, CHLORELLA VULGARIS EXTRACT, MARIS AQUA (SEA WATER), ISOBUTYLPARABEN, SILICA, DISODIUM SUCCINATE, CI 42090 (BLUE 1)

Purpose

Sunscreen

Call us toll-free: In the United States at 1-800-992-LBEL (5235), in Puerto Rico, 1-866-366-3235 (Metro area). US: Dis. by Ventura International Ltd.

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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. Noursih according to age

PROGRESSION JOUR

Protective complex with SPF 15

The skin is an organ that acts as the body's first line of defense against environmental aggressions. However, after the age of 30, the skin's natural self-defense properties diminish, making it more vulnerable to ultraviolet (UVA and UVB) rays, as well as to pollution, which can accelerate the aging process.

The skin does not recover as quickly as it once did. For that reason, it is essential to give your skin the protection it needs.

Regression Jour with Sun Protection Factor (SPF) 15, in addition to moisturizing the skin, acts as a shield to protect its youthful appearance.

Discover the effectiveness of its action

- **Protective Shield Complex:** Effective plant-derived complex that helps maintain the skin's natural defenses.
- **Hydra-Film Technology:** Seaweed extract that helps recover the skin's hydrolipid layer responsible for hydration, absorption and water retention to transport moisture to the skin cells that need it most.

In two options according to your skin's needs:

- Regression Jour protective complex with SPF 15 facial day cream normal to dry skin.
- Regression Jour protective complex with SPF 15 facial day cream normal to combination skin.

USES: Helps prevent sunburn.

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DIRECTIONS:

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- Reapply at least every 2 hours
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- Children under 6 months of age: Ask a doctor

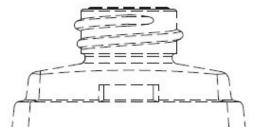
OTHER INFORMATION:

- Protect the product in this container from excessive heat and direct sun.
- Apply in the morning at the end of your skin care routine
- Apply with fingertips, spreading softly throughout the face until completely absorbed
- HYPOALLERGENIC
- CLINICALLY AND DERMATOLOGICALLY TESTED

After the age of 30

NEW REGRESSION JOUR Protective complex with SPF 15 facial day lotion normal to combination skin 50 ml e (1.6 fl. oz.) L'BEL

L'BEL REGRESSION JOUR Protective Complex With SPF 15 Facial Day Lotion Normal to Combination Skin

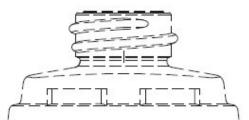


L'BEL

REGRESSION JOUR

protective complex with SPF 15 facial day lotion normal to combination skin

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ACTIVE INGREDIENTS:

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

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REGRESSION JOUR

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REGRESSION JOUR

protective complex with SPF 15

www.lbel.com



Drug Facts

Active Ingredients Purpose Octinoxate (7.5 %), Octisalate (4 %), Oxybenzone (4 %)

Uses ■ Heins prevent sunburn

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Sample not for sale

Drug Facts (continued)

Inactive ingredients

Aqua (water), glycine soja protein glycine soja (soybean) protein), c.12-15 alkyl benzate, pisum sativum estract (pisum sativum (pee) extract), cydohexasalxane, dimethicone, mannitot, estean) alkonich, divinimylol heyliketone crosspolymer, demonstration of the solid protein strength of the solid protein solid prote

Call us to free: In the United States at 1-600-992-LBEL (5235), in Puerto Rico, 1-886-968-9235 (island) or 622-9235 (Metro area).

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www.lbel.com

Regression Jour with Sun Protection Factor (SPF) 15, in addition to moisturizing the skin, acts as a shield to protect its youthful appearance. It works through two exclusive components: Protective Shield Complex and Hydra-Film Technology.

Drug Facts

Active Ingredients Purpose Octinoxate (7.5 %).....sunscreen Octisalate (4 %).....sunscreen Oxybenzone (4 %)sunscreen

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- Apply with the fingertips, spreading softly throughout the face until completely absorbed

Active ingredients

Aqua (water), glycine soja protein (glycine soja (soybean) protein), c12-15 alkyl benzoate, pisum sativum extract (pisum sativum (pea) extract), cyclohexasiloxane, dimethicone, mannitol, cetearyl alcohol, hdi/trimethylol hexylactone crosspolymer,

L'BEL

Drug Facts (continued)

phenoxyethanol, sodium acrylate/acryloyldimethylt aurate/dimethylacrylamide crosspolymer, c20-22 alkyl phosphate, glyceryl stearate, hydroxyethyl a c r y l a t e / s o d i u m acryloyldymethyl taurate copolymer, c20-22 alcohols, triethanolamine, sohexadecane methylparaben, c14-22 alcohols, ceteary l glucoside, hydrolyzed adansonia digitata extract, butylparaben, cyclopentasiloxane, chlorphenesin, xanthan gum, propylparaben, acrylates/c10-30 alkyl acrylate crosspolymer, disodium edta, parfum (fragrance), sorbic acid, polysorbate 60, cyclodextrin, c12-20 alkyl glucoside, faex extract (yeast extract), hydrolyzed algin, ethylparaben, chlorella vulgaris extract, maris aqua (sea water), isobutylparaben, silica, disodium succinate, CI 42090 (blue 1).

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MADE IN FRANCE

REGRESSION JOUR

protective complex with SPF 15 facial day lotion normal to combination skin

50 ml e (1.6 fl.oz.)

LBEL REGRESSION JOUR PROTECTIVE COMPLEX WITH SPF 15 FACIAL DAY NORMAL TO COMBINATION SKIN

octinoxate, octisalate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4 mL in 100 mL	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	4 mL in 100 mL	

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SOY PROTEIN (UNII: R44IWB3RN5)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PEA (UNII: W4X7H8GYFM)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
MANNITOL (UNII: 30WL53L36A)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
SODIUM ACRYLATE/SODIUM ACRYLO YLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
C20-22 ALKYL PHO SPHATE (UNII: L4VKP0 Y7RP)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
2-HYDRO XYETHYL ACRYLATE (UNII: 25GT92NY0C)	
C20-22 ALCOHOLS (UNII: O4M0347C6A)	
TROLAMINE (UNII: 9O3K93S3TK)	
ISOHEXADECANE (UNII: 918 X10 UF1E)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
C14-22 ALCOHOLS (UNII: B1K89384RJ)	
CETEARYL GLUCOSIDE (UNII: 09 FUA47KNA)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
SORBIC ACID (UNII: X045WJ989B)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
C12-20 ALKYL GLUCO SIDE (UNII: K67N5Z1RUA)	
YEAST (UNII: 3NY3SM6B8U)	
ETHYLPARABEN (UNII: 14255EXE39)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8 ZGC8 ISR3)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0003-0	1 mL in 1 POUCH		
2	NDC:43596-0003-1	5 mL in 1 JAR		
3	NDC:43596-0003-2	50 mL in 1 JAR		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	03/27/2012		

Labeler - Ventura Corporation, LTD (602751344)

Establishment			
Name	Address	ID/FEI	Business Operations
MF Productions		266769145	manufacture

Revised: 3/2012 Ventura Corporation, LTD