LBEL SUPREMACIE NX JOUR REPLENISHING TREATMENT DAYTIME FACE SPF 15 NORMAL TO DRY SKIN - ensulizole, homosalate, octinoxate, oxybenzone cream 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.

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Active Ingredients

ENSULIZOLE (2.0%) HOMOSALATE (2.0%) OCTINOXATE (7.5%) OXYBENZONE (4.0%)

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.

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.
- Reapply at least every 2 years.
- 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.

• Use in the morning after cleanser and toner. Apply a small quantity with your fingertips, spreading it over your face with rising, circular movements. Message in gently to help facilitate absorption.

Inactive Ingredients

Aqua (water), pisum sativum extract (pisum sativum (pea) extract), glycerin, cetyl alcohol, cyclopentasiloxane, triethanolamine, c12-15 alkyl benzoate, cyclohexasiloxane, glyceryl stearate, stearic acid, phenoxyethanol,polyacrylamide, erythritol,parfum (fragrance), peg-75 stearate, sodium polystyrene sulfonate,methylparaben, trifolium pratense flower extract(trifolium pratense (clover) flower extract), c13-14 isoparaffin,sorghum bicolor stalk juice, propylparaben, xanthan gum, ceteth-20, steareth-20, butylene glycol, laureth-7, acrylates/c10-30 alkyl acrylate crosspolymer, tetrasodium edta, dimethicone, butylparaben, hydrolyzed algin, ethylparaben, chlorella vulgaris extract, lecithin, maris aqua (sea water), isobutylparaben, carbomer, laureth-23, laureth-4, homarine hcl, ci 19140 (yellow 5),ci 14700 (red 4), biotinoyl tripeptide-1, ci 42090 (blue 1).

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.

SUPREMACIE NX JOUR

replenishing daytime face cream SPF 15

L'Bel, fully specialized in cosmetic facial treatment, presents the latest worldwide exclusive: the new Supremacie NX line of replenishing cosmetic treatments improved for women after age 40.

Dazzling beauty for women

The moisturizing formula of Supremacie NX Jour, Offers enhanced results:

- Immediate, strong and long-lasting hydration in the areas where the face needs it most.
- Visibly diminishes the appearance of wrinkles.
- Uncovers skin that looks more firm.

A sensation of well-being that pervades the senses

Its rich and creamy texture, ideal for absorption has been specially created to provide a pleasant sensation of softness and comfort. Its exquisite fragrance rich in essences awakens the skin with new and pleasant emotions.

In two options according to your skin's needs:

• SUPREMACIE NX JOUR - replenishing daytime face cream SPF 15 Normal to Dry Skin

• SUPREMACIE NX JOUR - replenishing daytime face cream SPF 15 Normal to Oily Skin

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. Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating. Children under 6 months of age: Ask a doctor.

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- HYPOALLERGENIC
- DERMATOLOGICALLY AND CLINICALLY TESTED

L'BEL SUPREMACIE NX JOUR

replenishing daytime face cream SPF 15 normal to dry skin

50 g e (1.7 oz..)

US: Dist. by Ventura International Ltd. DBA Belcorp USA, San Francisco, CA 94111.

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

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L'BEL

SUPREMACIE NX JOUR

replenishing daytime face cream SPF 15

www.lbel.com

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OTHER INFORMATION: Protect the product in this container from excessive heat and direct sun. Use in the morning after cleanser and toner. Apply a small quantity with your fingertips, spreading it over your face with rising, circular movements. Massage in gently to help facilitate absorption.

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MADE IN FRANCE

Drug Facts (continued)

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Drug Facts (continued)

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ychboxasicsane, glyceny stearate, stearic acid,
phenoxyethanol, polyacryfamide, erythritical
phenoxyethanol, polyacryfamide, erythritical
parfum (fragrance), peg-75 stearate, softion
polystyrene sulfonate, methylparaben, trifolium
polystyrene sulfonate, methylparaben, trifolium
polystyrene sulfonate, methylparaben, trifolium
polystyrene sulfonate, methylparaben, trifolium
polystyrene extract (frichier glycel, laureth-7,
acrylates/c10-30 alkyl acrylate crosspolymen,
carbomen, chareful paraben, hydrolyzed algin,
ethylparaben, chlorella vulgara estract, lecthin,
carbomen, laureth-23, laureth-4, homarine hol,
c1 19140 (yellow S), C1 14700 (red 4), biotinoyl
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Octinoxate (7.5%)	sunscreen
Oxybenzone (4.0%)	sunscreen

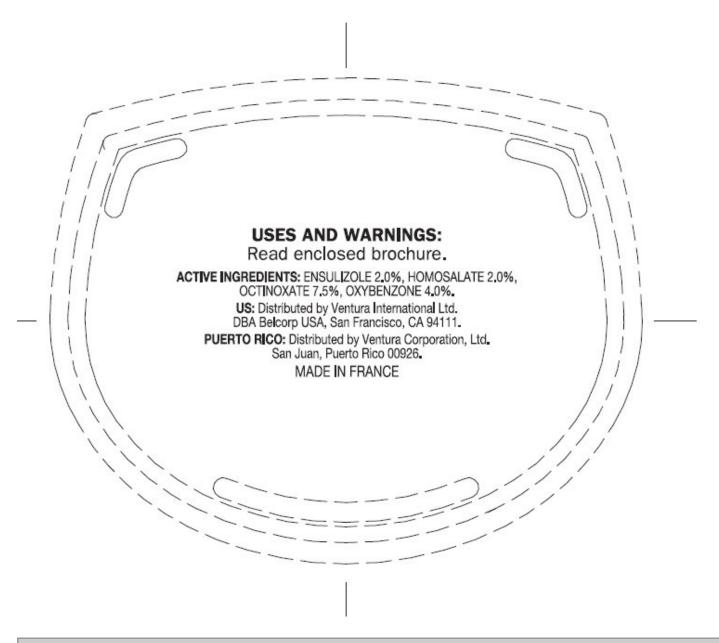
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ensulizole, homosalate, octinoxate, oxybenzone cream

Route of Administration

TOPICAL

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0005

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ENSULIZOLE (UNII: 9 YQ9 DI1W42) (ENSULIZOLE - UNII:9 YQ9 DI1W42)	ENSULIZOLE	2 g in 100 g		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2 g in 100 g		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g		
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	4 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PEA (UNII: W4X7H8GYFM)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ERYTHRITOL (UNII: RA96B954X6)	
PEG-75 STEARATE (UNII: OT38 R0 N74H)	
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
TRIFO LIUM PRATENSE FLO WER (UNII: 4JS0838828)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
SORGHUM BICOLOR STEM JUICE (UNII: SKN30 A29 4R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETETH-20 (UNII: I835H2IHHX)	
STEARETH-20 (UNII: L0Q8IK9E08)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
LAURETH-7 (UNII: Z95S6G8201)	
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
ISOBUTYLPARABEN (UNII: 0 QQJ25X58G)	
LAURETH-23 (UNII: N72LMW566G)	
LAURETH-4 (UNII: 6HQ855798J)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	
BIOTINO YL TRIPEPTIDE-1 (UNII: O6380721VA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0005-0	1 g in 1 POUCH		
2	NDC:43596-0005-1	5 g in 1 JAR		
3	NDC:43596-0005-2	50 g in 1 JAR		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	03/28/2012		

Labeler - Ventura Corporation, LTD (602751344)

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

Revised: 3/2012 Ventura Corporation, LTD