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

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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Active Ingredients

ENSULIZOLE (1.50%)
HOMOSALATE (1.00%)
OCTINOXATE (7.50%)
OXYBENZONE (4.50%)
TITANIUM DIOXIDE (1.17%)

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 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), cyclopentasiloxane, c12-15 alkyl benzoate, pisum sativum extract (pisum sativum (pea) extract), cyclohexasiloxane, triethanolamine, cetyl alcohol, glycerin, glyceryl stearate, propylene glycol, methyl methacrylate crosspolymer, peg-75 stearate, phenoxyethanol, erythritol, sodium polystyrene sulfonate, xanthan gum, parfum (fragrance), trifolium pratense flower extract (trifolium pratense (clover) flower extract), acrylates/c10-30 alkyl acrylate crosspolymer, ceteth-20, sorghum bicolor stalk juice, steareth-20, methylparaben, silica, methicone, butylparaben, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, stearic acid, chlorphenesin, butylene glycol, sorbic acid, tetrasodium edta, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, hydrolyzed algin, ethylparaben, dimethiconol, squalane, chlorella vulgaris extract, lecithin, maris aqua (sea water), isobutylparaben, propylparaben, carbomer, polysorbate 60, homarine hcl, ci 19140 (yellow 5), biotinoyl tripeptide-1, ci 14700 (red 4).

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.

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.

- HYPOALLERGENIC
- DERMATOLOGICALLY AND CLINICALLY TESTED

L'BEL SUPREMACIE NX JOUR

replenishing daytime face cream SPF 15 normal to oily skin

50 ml e (1.6 fl.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

L'BEL SUPREMACIE NX JOUR Replenishing Treatment Daytime Face Cream SPF 15 Normal To Oily Skin

L'BEL

SUPREMACIE NX JOUR

replenishing daytime face cream SPF 15

www.lbel.com

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1	2 Nourish				
Cleanse	Renovênce Jour	Renovênce Null	o J Renovânce Decolletage		o J Renovânce Veux

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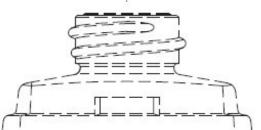
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DIRECTIONS: Apply liberally and evenly 15 minutes before sun exposure. Reapply at least every 2 hours, Use a water resistant sunscreen if swimming or sweating, Children under 6 months of age: Ask a doctor.

OTHER INFORMATION: Protect the product in this container from excessive heat and direct supply 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

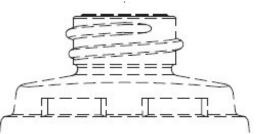


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ACTIVE INGREDIENTS:

Ensulizole (1.5%) Homosalate (1.0%) Ocytinoxate (7.5%) Oxybenzone (4.5%) Titanium dioxide (1.17%)

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MADE IN FRANCE

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Drug Facts

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Inactive Ingredients

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Drug Facts (continued)

extract (pisum sativum (pea) extract), cyclohexasiloxane, triethanolamine, cetyl alcohol, glycerin, glyceryl stearate, propylene glycol, methyl methacrylate crosspolymer, peg-75 stearate, phenoxyethanol, erythritol, sodium polystyrene sulfonate, xanthan gum, parfum (fragrance), trifolium pratense flower extract (trifolium pratense (clover) flower extract), acrylates/c10-30 alkyl acrylate crosspolymer, ceteth-20, sorghum bicolor stalk juice, steareth-20, methylparaben, silica, methicone, butylparaben, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, stearic acid, chlorphenesin, butylene glycol, sorbic acid, tetrasodium edta. hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, hydrolyzed algin, ethylparaben, dimethiconol, squalane, chlorella vulgaris extract, lecithin, maris aqua (sea water), isobutylparaben, propylparaben, carbomer, polysorbate 60, homarine hcl, CI 19140 (yellow 5), biotinoy tripeptide-1, CI 14700 (red 4).

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50 ml e (1.6 fl.oz.)

SPF 15 NORMAL TO OILY SKIN

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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43455-0006	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ENSULIZOLE (UNII: 9 YQ9 DI1W42) (ENSULIZOLE - UNII:9 YQ9 DI1W42)	ENSULIZOLE	1.5 mL in 100 mL			
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	1 mL in 100 mL			
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL			
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4.5 mL in 100 mL			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	1.17 mL in 100 mL			

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PEA (UNII: W4X7H8GYFM)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
TROLAMINE (UNII: 9O3K93S3TK)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-75 STEARATE (UNII: OT38R0N74H)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ERYTHRITOL (UNII: RA96B954X6)	
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRIFO LIUM PRATENSE FLO WER (UNII: 4JS0838828)	
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)	
CETETH-20 (UNII: 1835H2IHHX)	
SORGHUM BICOLOR STEM JUICE (UNII: SKN30A294R)	
STEARETH-20 (UNII: L0Q8IK9E08)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SORBIC ACID (UNII: X045WJ989B)	

ETHYLPARABEN (UNII: 14255EXE39)	
SQUALANE (UNII: GW89575KF9)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
ISOBUTYLPARABEN (UNII: 0 QQJ25X58G)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
BIOTINOYL TRIPEPTIDE-1 (UNII: O6380721VA)	
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:43455-0006-0	1 mL in 1 POUCH			
2	NDC:43455-0006-1	5 mL in 1 TUBE			
3	NDC:43455-0006-2	50 mL in 1 JAR			

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

Labeler - Ventura International, LTD (603192787)

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

Revised: 3/2012 Ventura International, LTD