

SUPREMACIE NX JOUR- ensulizole, homosalate, octinoxate, oxybenzone, and 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.

Suprémacie Nx Jour Replenishing Treatment Daytime Face Cream SPF 15 Normal to Oily Skin

ACTIVE INGREDIENTS: ENSULIZOLE 1.5%, HOMOSALATE 1.0 %, OCTINOXATE 7.5%, OXYBENZONE 4.5%, TITANIUM DIOXIDE 1.17%.

INACTIVE INGREDIENTS: AQUA (WATER), CYCLOPENTASILOXANE, C12-15 ALKYL BENZOATE, PISUM SATIVUM (PEA) EXTRACT, CYCLOHEXASILOXANE, GLYCERIN, CETYL ALCOHOL, TRIETHANOLAMINE, PROPYLENE GLYCOL, GLYCERYL STEARATE, METHYL METHACRYLATE CROSSPOLYMER, PHENOXYETHANOL, SODIUM POLYSTYRENE SULFONATE, ERYTHRITOL, PEG-75 STEARATE, XANTHAN GUM, PARFUM (FRAGRANCE), TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT, METHYLPARABEN, ACRYLATES/ C10-30 ALKYL ACRYLATE CROSSPOLYMER, SORGHUM BICOLOR STALK JUICE, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, STEARIC ACID, PROPYLPARABEN, SILICA, SQUALANE, METHICONE, STEARETH-20, CETETH-20, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, DIMETHICONE CROSSPOLYMER, CHLORPHENESIN, BUTYLENE GLYCOL, BUTYLPARABEN, SORBIC ACID, TETRASODIUM EDTA, ISOBUTYLPARABEN, ETHYLPARABEN, POLYSORBATE 60, HYDROLYZED ALGIN, DIMETHICONOL, CHLORELLA VULGARIS EXTRACT, MARIS AQUA (SEA WATER) , LECITHIN, CARBOMER, HOMARINE HCl, CI 19140 (YELLOW 5), BIOTINOYL TRIPEPTIDE-1, CI 14700 (RED 4).

INGREDIENTS: AQUA (WATER), ETHYLHEXYL METHOXYCINNAMATE, BENZOPHENONE-3, CYCLOPENTASILOXANE, C12-15 ALKYL BENZOATE, PISUM SATIVUM (PEA) EXTRACT, CYCLOHEXASILOXANE, GLYCERIN, CETYL ALCOHOL, TRIETHANOLAMINE, PHENYLBENZIMIDAZOLE SULFONIC ACID, TITANIUM DIOXIDE, PROPYLENE GLYCOL, HOMOSALATE, GLYCERYL STEARATE, METHYL METHACRYLATE CROSSPOLYMER, PHENOXYETHANOL, SODIUM POLYSTYRENE SULFONATE, ERYTHRITOL, PEG-75 STEARATE, XANTHAN GUM, PARFUM (FRAGRANCE), TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT, METHYLPARABEN, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, SORGHUM BICOLOR STALK JUICE, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, STEARIC ACID, PROPYLPARABEN, SILICA, SQUALANE, METHICONE, STEARETH-20, CETETH-20, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, DIMETHICONE CROSSPOLYMER, CHLORPHENESIN, BUTYLENE GLYCOL, BUTYLPARABEN, SORBIC ACID, TETRASODIUM EDTA, ISOBUTYLPARABEN, ETHYLPARABEN, POLYSORBATE 60, HYDROLYZED ALGIN, DIMETHICONOL, CHLORELLA VULGARIS EXTRACT, MARIS AQUA (SEA WATER), LECITHIN, CARBOMER, HOMARINE HCl, CI 19140 (YELLOW 5), BIOTINOYL TRIPEPTIDE-1, CI 14700 (RED 4).

USE: 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.

WARNING: For external use only. Avoid contact with eyes. Keep out of reach of children. If you observe any adverse reaction, discontinue use and consult your physician.

IMPORTANT: Provides moderate protection against sunburn.

- HYPOALLERGENIC.
- DERMATOLOGICALLY AND CLINICALLY TESTED.

PRINCIPAL DISPLAY PANEL - 50 mL Carton

**L'BEL
PARIS**

SUPRÉMACIE NX JOUR

traitement reconstituant
crème de jour pour le visage
fps 15
peau normale à grasse

replenishing treatment
daytime face cream spf 15
normal to oily skin

tratamiento reconstituyente
crema facial de día fps 15
cutis normal a graso

50 ml e (1.6 fl. oz.)

www.lbel.com

L'BEL
PARIS

ACTIVE INGREDIENTS: ENSULIZOLE 1.5%, HOMOSALATE 1.0%, OCTINOXATE 7.5%, OXYBENZONE 6%, TITANIUM DIOXIDE 11.1%.

INACTIVE INGREDIENTS: AQUA (WATER), CYCLOPENTASILOXANE, C12-15 ALKYL BENZOATE, PISUM SATIVUM (PEA) EXTRACT, CYCLOHEXASILOXANE, GLYCERIN, CETYL ALCOHOL, TRIETHANOLAMINE, PROPYLENE GLYCOL, GLYCERYL STEARATE, METHYL METHACRYLATE COPOLYMER, PHENOXYETHANOL, SODIUM POLYSTYRENE SULFONATE, ERYTHRITOL, PEG-75 STEARATE, XANTHAN GUM, PARFUM (FRAGRANCE), TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT, METHYL PARABEN, ACRYLATES/C10-30 ALKYL ACRYLATE COPOLYMER, SORGHUM BICOLOR STALK JUICE, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, STEARIC ACID, PROPYL PARABEN, SILICA, SQUALANE, METHICONE, STEARETH-20, CETETH-20, DIMETHICONE/VINYL DIMETHICONE COPOLYMER, DIMETHICONE COPOLYMER, CHLORPHENESIN, BUTYLENE GLYCOL, BUTYL PARABEN, SORBIC ACID, TETRASODIUM EDTA, ISOBUTYL PARABEN, ETHYL PARABEN, POLYSORBATE 60, HYDRALYZED ALGIN, DIMETHICONE, CHLORELLA VULGARIS EXTRACT, MAFIS AQUA (SEA WATER), LECITHIN, CARBOMER, HOMARINE HCl, CI 19140 (YELLOW 5), BIOTINYL TRIPEPTIDE-1, CI 14700 (RED 4).

INGREDIENTS: AQUA (WATER), ETHYLHEXYL METHOXYCINAMATE, BENZOPHENONE-3, CYCLOPENTASILOXANE, C12-15 ALKYL BENZOATE, PISUM SATIVUM (PEA) EXTRACT, CYCLOHEXASILOXANE, GLYCERIN, CETYL ALCOHOL, TRIETHANOLAMINE, PHENYLBENZIMIDAZOLE SULFONIC ACID, TITANIUM DIOXIDE, PROPYLENE GLYCOL, HOMOSALATE, GLYCERYL STEARATE, METHYL METHACRYLATE COPOLYMER, PHENOXYETHANOL, SODIUM POLYSTYRENE SULFONATE, ERYTHRITOL, PEG-75 STEARATE, XANTHAN GUM, PARFUM (FRAGRANCE), TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT, METHYL PARABEN, ACRYLATES/C10-30 ALKYL ACRYLATE COPOLYMER, SORGHUM BICOLOR STALK JUICE, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, STEARIC ACID, PROPYL PARABEN, SILICA, SQUALANE, METHICONE, STEARETH-20, CETETH-20, DIMETHICONE/VINYL DIMETHICONE COPOLYMER, DIMETHICONE COPOLYMER, CHLORPHENESIN, BUTYLENE GLYCOL, BUTYL PARABEN, SORBIC ACID, TETRASODIUM EDTA, ISOBUTYL PARABEN, ETHYL PARABEN, POLYSORBATE 60, HYDRALYZED ALGIN, DIMETHICONE, CHLORELLA VULGARIS EXTRACT, MAFIS AQUA (SEA WATER), LECITHIN, CARBOMER, HOMARINE HCl, CI 19140 (YELLOW 5), BIOTINYL TRIPEPTIDE-1, CI 14700 (RED 4).

INGREDIENTS: AQUA, ETIL METOKSINAMATO DE BENILO, BENZOFENONA-3, CICLOPENTASILOXANO, C12-15 ALQUIL BENZOATO, EXTRACTO DE QUISANTE (PISUM SATIVUM), CICLOHEXASILOXANO, GLICERINA, ALCOHOL CETILICO, TRIETANOLAMINA, ACIDO FENILBENZIMIDAZOLSULFONICO, DIOXIDO DE TITANIO, PROPILENGlicol, HOMOSALATO, ESTEARATO DE GLICERIL, COPOLIMERO DE METILMETACRILATO, FENOXIETANOL, PUESTREN SULFONATO DE SODIO, ETRITOL, PEG-75 ESTEARATO, GOMA XANTANA, FRAGRANCIA, EXTRACTO DE FLOR DE TRESBOL (TRIFOLIUM PRATENSE), METILPARABENO, COPOLIMERO DE ACRILATO/C10-30 ALQUIL ACRILATO, JUGO DE TALLO DE SORGHUM BICOLOR, COPOLIMERO DE ACRILATO DE HIDROXETILACRILATO/DIMETIL TAURATO DE SODIO, ACIDO ESTEARICO, PROPILPARABENO, SLICE, ESQUALANO, METICONA, ESTARET-20, CETEF-20, DIMETICONA/VINIL DIMETICONA COPOLIMERO, DIMETICONA COPOLIMERO, CLORFENESINA, BUTILENGlicol, BUTILPARABENO, ACIDO SORBICO, EDTA TETRASODICO, ISOBUTILPARABENO, ETILPARABENO, POLISORBATO 60, ALGINA HIDRALIZADA, DIMETICONA, EXTRACTO DE CHLORELLA VULGARIS, AGUA DE MAR, LECITINA, CARBOMER, HIDROCLORURO DE HOMARINA, ANARANILLO CI 19140, BIODINIL TRIPEPTIDO-1, ROJO 14700.

USE: 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.

WARNING: For external use only. Avoid contact with eyes. **Keep out of reach of children.** If you observe any adverse reaction, discontinue use and consult your physician.

IMPORTANT: Provides moderate protection against sunburn.

- HYPOALLERGENIC.
- DERMATOLOGICALLY AND CLINICALLY TESTED.

USO: Utilizar por las mañanas luego de la limpiadora y la tónica. Aplicar con la yema de los dedos en pequeñas cantidades, esparcir por el rostro con movimientos circulares ascendentes. Frotar suavemente para favorecer su completa absorción.

ADVERTENCIA: Exclusivo uso externo. Evitar el contacto con los ojos. **Mantener alejado del alcance de los niños.** Si se observa alguna reacción desfavorable, suspender el uso y consultar con un médico.

IMPORTANTE: Provee moderada protección contra los rayos solares.

- HIPOALERGÉNICO.
- DERMATOLÓGICA Y CLÍNICAMENTE PROBADO.

US: Distributed by Ventura International Ltd, San Francisco, CA 94111.
PUERTO RICO: Distributed by Ventura Corporation, Ltd, San Juan, Puerto Rico 00906.

MADE IN FRANCE



SUPRÉMACIE NX JOUR

traitement reconstituant
crème de jour pour le visage
fps 15
peau normale à grasse

replenishing treatment
daytime face cream spf 15
normal to oily skin

tratamiento reconstituyente
crema facial de día fps 15
cutis normal a graso

50 ml e (1.6 fl.oz.)

SUPREMACIE NX JOUR

ensulizole, homosalate, octinoxate, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-093
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ensulizole (UNII: 9YQ9D11W42) (Ensulizole - UNII:9YQ9D11W42)	Ensulizole	0.00075 g in 5 mL
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	0.001 g in 5 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.00375 g in 5 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.00225 g in 5 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.000585 g in 5 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-093-94	1 in 1 BOX		
1	NDC:14783-093-93	5 mL in 1 TUBE		
2	NDC:14783-093-96	1 in 1 BOX		
2	NDC:14783-093-95	50 mL in 1 JAR		
3	NDC:14783-093-97	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	01/04/2010	

Labeler - Ventura International LTD (603192787)

Revised: 2/2010

Ventura International LTD