

**LBEL SUPREMACIE MAINS- ensulizole, octinoxate, and oxybenzone 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.

**L'BEL
SUPRÉMACIE
MAINS**

Drug Facts

Active Ingredients

Ensulizole (3 %), Octinoxate (7.5%), Oxybenzone (2 %)

Purpose

Sunscreen

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

- moderate sun protection product.
- apply smoothly every morning before sun exposure and as needed.
- apply a small amount of the product to the back of clean, dry hands. Massage softly until completely absorbed.
- children under 6 months of age: ask a doctor.

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.

Inactive ingredients

Aqua (water), c12-15 alkyl benzoate, cyclopentasiloxane, saccharomyces/xylinum/black tea ferment, triethanolamine, glycerin, cyclohexasiloxane, cetyl alcohol, glyceryl stearate, cetearyl alcohol, talc, propyleneglycol, peg-100 stearate, parfum (fragrance), diazolidinyl urea, phenyl trimethicone, sodium lactate, acrylates/c10-30 alkylacrilate crosspolymer, cetareth-20, hydroxyethylcellulose, methylparaben, propylparaben, butylene glycol, hydrolyzed keratin, arctostaphylos uva ursi/leaf extract, panthenol, citrus unshiu peel extract, dimethicone crosspolymer, dimethicone/vinyl dimethicone crosspolymer, ci 77891 (titanium dioxide), tetrasodium edta, dimethiconol, phenoxyethanol, nymphaea coerulea flower extract, ci 19140 (yellow 5), ci 14700 (red 4), butylparaben, ethylparaben, isobutylparaben.

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

PRINCIPAL DISPLAY PANEL - 100 ml Carton

L'BEL

SUPRÉMACIE

MAINS

replenishing treatment

hand cream spf 15

100 ml e (3.3 fl.oz.)

Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	6.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
c12-15 alkyl benzoate (UNII: A9EJ3J61HQ)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
tea leaf (UNII: GH42T47V24)	
trolamine (UNII: 9O3K93S3TK)	
glycerin (UNII: PDC6A3C0OX)	
cyclomethicone 6 (UNII: XHK3U310BA)	
cetyl alcohol (UNII: 936JST6JCN)	
glyceryl monostearate (UNII: 230OU9XXE4)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
talc (UNII: 7SEV7J4RIU)	
propylene glycol (UNII: 6DC9Q167V3)	
polyoxyl 100 stearate (UNII: YD01N1999R)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
sodium lactate (UNII: TU7HW0W0QT)	
polyoxyl 20 cetostearyl ether (UNII: YRC528SWUY)	
methylparaben (UNII: A218C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
butylene glycol (UNII: 3XUS85K0RA)	
arctostaphylos uva-ursi leaf (UNII: 3M5V3D1X36)	
panthenol (UNII: WV9CM0O67Z)	
tangerine (UNII: KHBE3096OO)	
dimethicone (UNII: 92RU3N3Y1O)	
titanium dioxide (UNII: 15FIX9V2JP)	
edetate sodium (UNII: MP1J8420LU)	
phenoxyethanol (UNII: HIE492ZZ3T)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
butylparaben (UNII: 3QPII1U3FV8)	
ethylparaben (UNII: 14255EXE39)	
isobutylparaben (UNII: 0QQJ25X58G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-072-61	1 in 1 BOX		
1	NDC:14783-072-62	100 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/15/2010	

LBEL SUPREMACIE MAINS

ensulizole, octinoxate, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-062
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ensulizole (UNII: 9YQ9D11W42) (Ensulizole - UNII:9YQ9D11W42)	Ensulizole	0.15 g in 5 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.38 g in 5 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.31 g in 5 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
c12-15 alkyl benzoate (UNII: A9EJ3J61HQ)	
cyclomethicone 5 (UNII: 0THT5PCI0R)	
tea leaf (UNII: GH42T47V24)	
trolamine (UNII: 9O3K93S3TK)	
glycerin (UNII: PDC6A3C0OX)	
cyclomethicone 6 (UNII: XHK3U310BA)	
cetyl alcohol (UNII: 936JST6JCN)	
glyceryl monostearate (UNII: 230OU9XXE4)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
talc (UNII: 7SEV7J4R1U)	
propylene glycol (UNII: 6DC9Q167V3)	
polyoxyl 100 stearate (UNII: YD01N1999R)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
sodium lactate (UNII: TU7HW0W0QT)	
polyoxyl 20 cetostearyl ether (UNII: YRC528SWUY)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
butylene glycol (UNII: 3XUS85K0RA)	
arctostaphylos uva-ursi leaf (UNII: 3M5V3D1X36)	
panthenol (UNII: WV9CM0O67Z)	
tangerine (UNII: KH3E3096OO)	
dimethicone (UNII: 92RU3N3Y1O)	
titanium dioxide (UNII: 15FIX9V2JP)	
edetate sodium (UNII: MP1J8420LU)	
phenoxyethanol (UNII: HIE492ZZ3T)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

butylparaben (UNII: 3QPIU3FV8)

ethylparaben (UNII: 14255EXE39)

isobutylparaben (UNII: 0QQJ25X58G)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-062-51	1 in 1 BOX		
1	NDC:14783-062-52	5 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	08/15/2010	

Labeler - VENTURA INTERNATIONAL LTD., (603192787)

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