LUMINOUS INTENSIVE DECOLLOTE TREATMENT SPF 20- avobenzone, octinoxate, and octis alate lotion

Erno Laszlo, Inc.

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.

Luminous Intensive Decollote Treatment SPF 20

Drug Facts

Active Ingredients

Avobenzone 2%, Octinoxate 7.5%, Octisalate 5%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

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 product is swallowed, get medical help or contact a Poison Control center right away.

Directions

Apply liberally 15 minutes before sun exposure

- reapply: after 40 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m. 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Inactive Ingredients

Cyclomethicone, Dimethicone Crosspolymer, Polysilicone-11, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Salicylic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl

Acetate, Retinyl Palmitate, Fragrance, Isopropylparaben, Isobutylparaben, Butylparaben.

Other information

• protect this product from excessive heat and direct sun

Questions or comments?

Call toll free at 866-452-7956.

DISTRIBUTED IN U.S.A. BY ERNO LASZLO NEW YORK, NY 10001

PRINCIPAL DISPLAY PANEL - 50 mL Jar Carton

ERNO

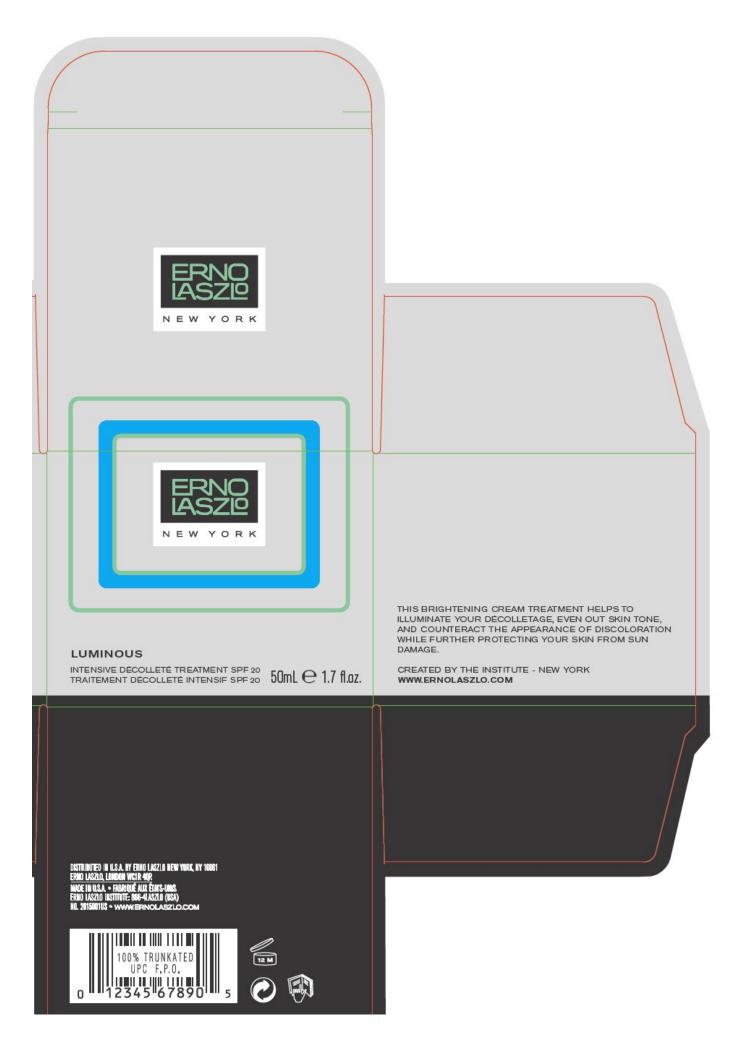
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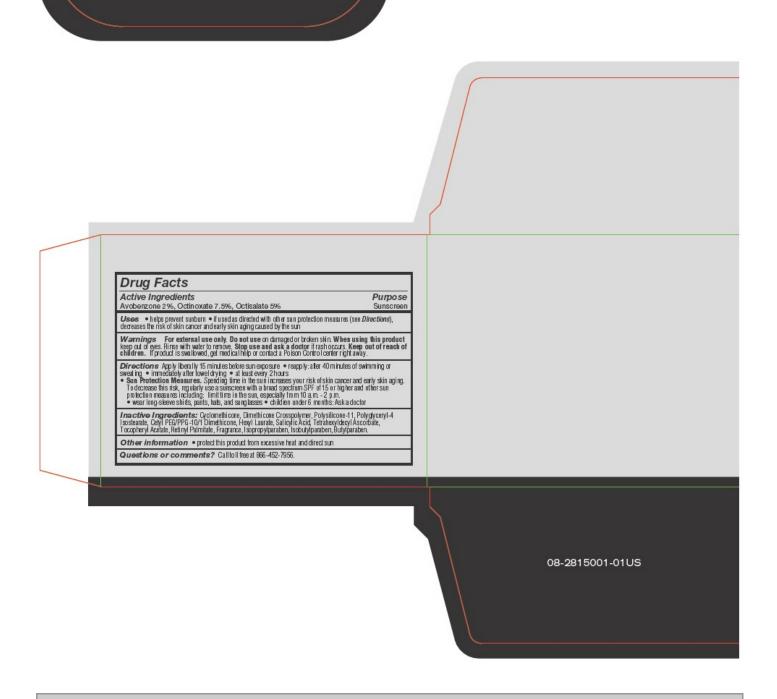
NEW YORK

LUMINOUS

INTENSIVE DÉCOLLETÉ TREATMENT SPF 20

50mL e 1.7 fl.oz.





LUMINOUS INTENSIVE DECOLLOTE TREATMENT SPF 20

avobenzone, octinoxate, and octisalate lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:579 13-28 15
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	20 mg in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 mL
Octisalate (UNII: 4X49 Y0596W) (Octisalate - UNII:4X49 Y0596W)	Octisalate	50 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
Cyclomethicone (UNII: NMQ347994Z)		
Polyglyceryl-4 Isostearate (UNII: 820 DPX33S7)		
Hexyl Laurate (UNII: 4CG9F9W01Q)		
Salicylic Acid (UNII: O414PZ4LPZ)		
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)		
.AlphaTocopherol Acetate (UNII: 9E8X80D2L0)		
Vitamin A Palmitate (UNII: 1D1K0N0VVC)		
Isopropylparaben (UNII: A6EOX47QK0)		
Isobutylparaben (UNII: 0QQJ25X58G)		
butylparaben (UNII: 3QPI1U3FV8)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:57913-2815-0	1 in 1 CARTON		
1	50 mL in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	04/10/2013	

Labeler - Erno Laszlo, Inc. (098821031)

Establishment			
Name	Address	ID/FEI	Business Operations
Mana Products		078870292	MANUFACTURE(579 13-28 15), LABEL(579 13-28 15), PACK(579 13-28 15)

Revised: 4/2013 Erno Laszlo, Inc.