

LUMINOUS INTENSIVE HAND TREATMENT SPF 25- avobenzone, octinoxate, and octisalate 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 Hand Treatment SPF 25

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

Water, Butyrospermum Parkii (Shea Butter), Octyldodecyl Neopentanoate, Cetyl Alcohol, Propylene Glycol, Glyceryl Stearate, PEG-100 Stearate, Cyclomethicone, Steareth-20, Ceteth-20, Persea

Gratissima (Avocado) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Taraktogenos Kurzii Seed Oil, Glycerin, Centella Asiatica Extract, Echinacea Purpurea Extract, Saxifraga Sarmentosa Extract, Vitis Vinifera (Grape) Fruit Extract, Morus Nigra Root Extract, Scutellaria Baicalensis Root Extract, Algae Extract, Fragrance, Carbomer, Phenoxyethanol, Isopropylparaben, Isobutylparaben, Butylparaben, Sodium Hydroxide.

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 - 100 mL Tube Carton

**ERNO
LASZLO**

NEW YORK

LUMINOUS

INTENSIVE HAND TREATMENT

SPF 25

100mL e 3.3 fl.oz.



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ERNO LASZLO INSTITUTE: 866-4LASZLO (USA)
NO. 2833927US • WWW.ERNO.LASZLO.COM

THIS BRIGHTENING HAND CREAM TREATMENT HELPS TO COUNTERACT HYPERPIGMENTATION, WHILE HYDRATING AND PROTECTING YOUR SKIN FROM SUN DAMAGE.

CREATED BY
THE INSTITUTE -
NEW YORK
WWW.ERNO.LASZLO.COM

LUMINOUS

INTENSIVE HAND TREATMENT
SPF 25
TRAITEMENT INTENSIF POUR
LES MAINS SPF 25

100mL e 3.3 fl.oz.

08-2833927-01 US





LUMINOUS INTENSIVE HAND TREATMENT SPF 25

avobenzone, octinoxate, and octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:579 13-2525
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: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SHEA BUTTER (UNII: K49155WL9Y)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
STEARETH-20 (UNII: L0Q8IK9E08)	
CETETH-20 (UNII: I835H2IHHX)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
JOJOBA OIL (UNII: 724GKU717M)	
HYDNOCARPUS KURZII SEED OIL (UNII: N757YEZ18Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	
WINE GRAPE (UNII: 3GOV20705G)	
MORUS NIGRA ROOT (UNII: 033456LFG1)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ISOPROPYL PARABEN (UNII: A6EOX47QK0)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
BUTYL PARABEN (UNII: 3QPII03FV8)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:579 13-2525-9	1 in 1 CARTON		
1		100 mL in 1 TUBE		

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 13-2525) , LABEL(579 13-2525) , PACK(579 13-2525)

Revised: 4/2013

Erno Laszlo, Inc.