

PHELITYL DAY SPF 15- avobenzone and octinoxate 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.

Phelityl Day SPF 15

Drug Facts

Active Ingredients

Avobenzone 2%, Octinoxate 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, Glyceryl Stearate, Butylene Glycol, Cetyl Alcohol, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Octyldodecyl Neopentanoate, Silica, Butyrospermum Parkii (Shea) Butter, Emu Oil, Glycerin, PEG-100 Stearate, Polyglyceryl-3 Laurate, Taraktogenos Kurzii Seed Oil, Aloe Barbadensis Leaf

Extract, Anthemis Nobilis Flower Extract, Camellia Sinensis Leaf Extract, Panax Ginseng Root Extract, Allantoin, Carbomer, Ceteth-20, Disodium EDTA, Ethylhexylglycerin, O-Cymen-5-Ol, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Fragrance, Steareth-2, Steareth-20, Triethanolamine, Phenoxyethanol.

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 - 90mL Jar Carton

**ERNO
LASZLO**

NEW YORK

PHELITYL

DAY LOTION SPF 15

90mL e 3.0 fl.oz.



ERNO LASZLO TIMELESS SKIN SYSTEM, OUR TWICE-DAILY RITUAL OF CLEANSING, TONING, MOISTURIZING AND FINISHING, PROMOTES THE ESSENTIAL HEALTH AND CONTINUAL RENEWAL OF YOUR SKIN, TO MAINTAIN A YOUTHFUL APPEARANCE.

THIS WEIGHTLESS, VITAMIN-RICH PREPARATION HELPS TO REDUCE FINE LINES, SOFTEN AND SOOTHE YOUR SKIN.

PHELITYL
DAY LOTION SPF 15

DAY LOTION SPF 15
FLUIDE HYDRATANT SPF 15

90mL e 3.0 fl.oz.

CREATED BY
THE INSTITUTE -
NEW YORK
WWW.ERNOLASZLO.COM

DISTRIBUTED IN U.S.A. BY
ERNO LASZLO NEW YORK, NY 10001
ERNO LASZLO, LONDON WC1R 4QR



MADE IN U.S.A.
FABRIQUÉ AUX ÉTATS-UNIS
ERNO LASZLO INSTITUTE:
866-4LASZLO (USA)
NO. 2832901US
WWW.ERNOLASZLO.COM



Drug Facts

Active Ingredients	Purpose
Avobenzone 2%, Octinoxate 5%	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.

or contact your health care provider 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, Glyceryl Stearate, Butylene Glycol, Cetyl Alcohol, Cyclopentasiloxane, C-12-15 Alkyl Benzoate, Octyldodecyl Neopentanoate, Silica, Butyrospermum Parkii (Shea) Butter, Emu Oil, Glycerin, PEG-100 Stearate, Polyglyceryl-3 Laurate, Taraktogenos Kurzii Seed Oil, Aloe Barbadensis Leaf Extract, Anthemis Nobilis Flower Extract, Camellia Sinensis Leaf Extract, Panax Ginseng Root Extract, Allantoin, Carbomer, Ceteth-20, Disodium EDTA, Ethylhexylglycerin, O-Cymen-5-OL, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Fragrance, Steareth-2, Steareth-20, Triethanolamine, Phenoxethanol.

Other information • protect this product from excessive heat and direct sun

Questions or comments? Call toll free at 866-452-7956.

3

TIMELESS SKIN SYSTEM

MOISTURIZE

DAY

NORMAL / COMBINATION SKIN

08-1127-ny

PHELITYL DAY SPF 15

avobenzone and octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57913-2832
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	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Cyclomethicone 5 (UNII: 0THT5PC10R)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Octyldodecyl Neopentanoate (UNII: X8725R883T)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Shea Butter (UNII: K49155WL9Y)	
Emu Oil (UNII: 344821WD61)	
Glycerin (UNII: PDC6A3C0OX)	
PEG-100 Stearate (UNII: YD01N1999R)	
Myristyl Alcohol (UNII: V42034O9PU)	
Coco Glucoside (UNII: ICS790225B)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Dimethicone (UNII: 92RU3N3Y1O)	
Hydnocarpus Kurzii Seed Oil (UNII: N757YEZ18Q)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Chamaemelum Nobile Flower (UNII: O2T154T6OG)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Asian Ginseng (UNII: CUQ3A77YXI)	
Allantoin (UNII: 344S277G0Z)	
Ceteth-20 (UNII: I835H2IHHX)	
Edetate Disodium (UNII: 7FLD91C86K)	
O-Cymen-5-Ol (UNII: H41B6Q1I9L)	
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Steareth-2 (UNII: V56DFE46J5)	
Steareth-20 (UNII: L0Q8IK9E08)	
Trolamine (UNII: 9O3K93S3TK)	
Phenoxyethanol (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57913-2832-9	1 in 1 CARTON		
1		90 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 13-2832) , LABEL(579 13-2832) , PACK(579 13-2832)

Revised: 4/2013

Erno Laszlo, Inc.