

HYDRAPHEL DAY SPF15- avobenzone and octinoxate cream

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.

Hydraphel Day SPF15

Drug Facts

Active Ingredients

Avobenzone 2%, Octinoxate 7.5%

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, Dimethicone, Cetearyl Alcohol, C12-15 Alkyl Benzoate, Hydrogenated Polyisobutene, Glyceryl Stearate, PEG-100 Stearate, Glycerin Soja (Soybean) Oil, Hydrogenated Cottenseed Oil, Taraktogenos Kurzii Seed Oil, Polyglyceryl-4 Isostearate, Brassica Campestris/Aleurites Fordi Oil Copolymer,

Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Hydrogenated Olive Oil, Tocopheryl Acetate, Retinyl Palmitate, PEG-40 Castor Oil, Magnesium Ascorbyl Phosphate, Sodium Hyaluronate, Disodium EDTA, Allantoin, Carbomer, Triethanolamine, Sodium Dehydroacetate, Phenoxyethanol, Caprylyl Glycol, Hexylene Glycol.

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
LASZLO**

NEW YORK

HYDRAPHEL

DAY CREAM SPF 15

50mL e 1.7 fl.oz.



HYDRAPHEL

DAY CREAM SPF 15
CRÈME DE JOUR SPF 15

50mL e 1.7 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 ULTRA-RICH PREPARATION PROTECTS AND RENEWS YOUR SKIN.

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

DISTRIBUTED IN U.S.A. BY ERNO LASZLO NEW YORK, NY 10001
ERNO LASZLO, LONDON W1G 9QR
MADE IN U.S.A. • FABRIQUÉ AUX ÉTATS-UNIS
ERNO LASZLO INSTITUTE: 000-0LASZLO (USA)
NO. 2000001US • WWW.ERNOLASZLO.COM





Drug Facts

Active Ingredients Avobenzone 2%, Octinoxate 7.5%	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, Dimethicone, Cetearyl Alcohol, C12-15 Alkyl Benzoate, Hydrogenated Polyisobutene, Glycerol Stearate, PEG-100 Stearate, Glycerin Soja (Soybean) Oil, Hydrogenated Cottonseed Oil, Taraxacogenos Kurzii Seed Oil, Polyglyceryl-4 Isostearate, Brassica Campestris/Aleurites Fordii Oil Copolymer, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Hydrogenated Olive Oil, Tocopheryl Acetate, Retinyl Palmitate, PEG-40 Castor Oil, Magnesium Ascorbyl Phosphate, Sodium Hyaluronate, Disodium EDTA, Allantoin, Carbomer, Triethanolamine, Sodium Dehydroascorbate, Phenoxysthanol, Caprylyl Glycol, Hexylene Glycol.	
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
DRY SKIN

08-1125-ny

HYDRAPHEL DAY SPF15

avobenzone and octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:579 13-2869
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

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Soybean Oil (UNII: 241ATL177A)	
Hydrogenated Cottonseed Oil (UNII: Z82Y2C65EA)	
Hdnocarpus Kurzii Seed Oil (UNII: N757YEZ18Q)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Hexyl Laurate (UNII: 4CG9F9W01Q)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
PEG-40 Castor Oil (UNII: 4ERD2076EF)	
Magnesium Ascorbyl Phosphate (UNII: 0R822556M5)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Edetate Disodium (UNII: 7FLD91C86K)	
Allantoin (UNII: 344S277G0Z)	
Trolamine (UNII: 9O3K93S3TK)	
Sodium Dehydroacetate (UNII: 8W46YN971G)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Hexylene Glycol (UNII: KEH0A3F75J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57913-2869-9	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(57913-2869) , LABEL(57913-2869) , PACK(57913-2869)