# 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.

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## **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 SPF15**

avobenzone and octinoxate cream

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:57913-2869
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Avobenzone (Avobenzone)	Avobenzone	20 mg in 1 mL	
Octinoxate (Octinoxate)	Octinoxate	75 mg in 1 mL	

# Inactive Ingredients

Ir	ngredient Name	Strength
Water		
Dimethicone		
Cetostearyl Alcohol		
Alkyl (C12-15) Benzoate		
Glyceryl Monostearate		
Soybean Oil		
Hydrogenated Cottonseed Oil		
Hydnocarpus Kurzii Seed Oil		
Polyglyceryl-4 Isostearate		
Hexyl Laurate		
.AlphaTocopherol Acetate		
Vitamin A Palmitate		
PEG-40 Castor Oil		
Magnesium Ascorbyl Phosphate		
Hyaluronate Sodium		
Edetate Disodium		
Allantoin		
Trolamine		
Sodium Dehydroacetate		
Phenoxyethanol		
Caprylyl Glycol		
Hexylene Glycol		

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)

Revised: 4/2013 Erno Laszlo, Inc.