

R.E.M. DAY SPF 30- 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.

R.E.M. Day SPF 30

Drug Facts

Active Ingredients

Avobenzone 3.0%, Octinoxate 7.5%, Octisalate 5.0%

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, C12-15 Alkyl Benzoate, Octyldodecyl Neopentanoate, Butylene Glycol, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Beeswax, Bisabolol, Ethylhexylglycerin, Hydroxyethylcellulose, Lecithin, Micrococcus Lysate, Retinyl Palmitate,

Tocopheryl Acetate, Tetrahexyldecyl Ascorbate, Corylus Avellana (Hazel) Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Persea Gratissima (Avocado) Oil, Sesamum Indicum (Sesame) Seed Oil, Taraktogenos Kurzii Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Ginkgo Biloba Leaf Extract, Aloe Barbadensis Leaf Extract, Panax Ginseng Root Extract, Centella Asiatica Extract, Echinacea Purpurea Extract, Algae Extract, Plankton Extract, Sodium Hyaluronate, Sodium PCA, Steareth -20, Disodium EDTA, Phenoxyethanol, O-Cymen-5-Ol, Fragrance.

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 - 90 mL Bottle Carton

**ERNO
LASZLO**

NEW YORK

R.E.M.

DAY LOTION SPF 30

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.

REPAIR. ENERGIZE. MOISTURIZE. THIS LIGHTWEIGHT MOISTURIZER EFFORTLESSLY DOES ALL THREE WHILE PROTECTING YOUR SKIN FROM SUN DAMAGE.

R.E.M.V.

DAY LOTION SPF 30
FLUIDE HYDRATANT SPF 30

90mL e 3.0 fl.oz.

FROM SUN DAMAGE.

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. 2834909US
WWW.ERNOLASZLO.COM



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TIMELESS SKIN SYSTEM

MOISTURIZE

DAY

DRY SKIN

08-2834909-01US

R.E.M. DAY SPF 30

avobenzone, octinoxate, and octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57913-2834
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 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: 059QF0K00R)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Octyldodecyl Neopentanoate (UNII: X8725R883T)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Glycerin (UNII: PDC6A3C0OX)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
PEG-100 Stearate (UNII: YD01N1999R)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Levomenol (UNII: 24WE03BX2T)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
European Hazelnut Oil (UNII: 8RQ2839AVG)	
Sunflower Oil (UNII: 3W1JG795YI)	
Avocado Oil (UNII: 6VNO72PFC1)	
Sesame Oil (UNII: QX10HYY4QV)	
Hydnocarpus Kurzii Seed Oil (UNII: N757YEZ18Q)	
Jojoba Oil (UNII: 724GKU717M)	
Ginkgo (UNII: 19FUJ2C58T)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Asian Ginseng (UNII: CUQ3A77YXI)	
Centella Asiatica (UNII: 7M867G6T1U)	
Echinacea Purpurea (UNII: QI7G114Y98)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Sodium Pyrrolidone Carboxylate (UNII: 469OTG57A2)	
Steareth-20 (UNII: L0Q8IK9E08)	
Edetate Disodium (UNII: 7FLD91C86K)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
O-Cymen-5-Ol (UNII: H41B6Q119L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57913-2834-9	1 in 1 CARTON		
1		90 mL in 1 BOTTLE		

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 13-2834) , LABEL(579 13-2834) , PACK(579 13-2834)

Revised: 4/2013

Erno Laszlo, Inc.