

ELTAMD UV SPF35- octinoxate, zinc oxide sunscreen lotion
CP Skin Health Group, Inc

EltAMD UV SPF35

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 physician if rash occurs. If product is swallowed get medical help or contact a Poison Control Center right away.

Active ingredients

Octinoxate 7.5% Sunscreen
Zinc Oxide 9.0% Sunscreen

Indications & Uses:

Helps prevent sunburn. If used as directed with other sun protection measure (See Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Indications & Uses:

Helps prevent sunburn. If used as directed with other sun protection measure (See Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Keep out of reach of children

Keep out of reach of children

Directions

Apply liberally 15 minutes before sun exposure. Use a water-resistant sunscreen if swimming or sweating. Reapply 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 am to 2 pm. Wear long-sleeve shirts, pants, hats, and sunglasses. Children under 6 months: ask a physician.

Other information:

Protect this product from excessive heat and direct sun.

Inactive ingredients

water, petrolatum, isopropyl palmitate, ethylhexyl stearate, dimethicone, phenoxyethanol, glyceryl stearate, PEG-100 stearate, oleth-3 phosphate, cetearyl alcohol, cetearyl glucoside, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, polyisobutene, polyether-1, ethylhexylglycerin, PEG-7 trimethylolpropane coconut ether, citric acid, tocopheryl acetate, sodium hyaluronate, triethoxycaprylylsilane

Questions?

Call toll free 1-800-633-8872

Labeling

American Carton Company
 807 South Waterloo St.
 Mansfield, Texas 75083
 Phone: 817.477.1933
 Fax: 817.478.0883

ACC DIE KO 10416 75-10 412 Skin Variant

Customer: Swiss American
 Description: 7414719_RD006785SH_PS0062993_EltaMD_Suncare_USA_UV_Lotion_8oz
 CAD #: A9805 SUBSTRATE: SBS
 ACC Item #: SA0722_RM10156
 Date: 01-16-2024

Revision Number: 0
 Pool Output Date: _____

UPC
 PIC

Please check all components of part (i.e. color, printing, etc.), fill out proper information below, and return to American Carton Company. The form and any form of proof (i.e. style, layout, artwork, color key, etc.) must be returned to ACC before job will proceed any further.

DELAYING RETURN OF PROOFS MAY DELAY DELIVERY OF YOUR JOB.

OK, AS IS
 No responsibility for error is assumed by ACC when printed per customer's approval.

SHOW REVISED PROOF
 If revised proofs are required, request must be made when this proof is returned.

Thank you to American Carton Company for proofed and delivered by my choice above.

Signature: _____ Date: _____



Drug Facts

| Active Ingredients | Purpose |
|--------------------|-----------|
| Octinoxate 7.5% | Sunscreen |
| Zinc Oxide 7.0% | 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 physician 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
- use a water-resistant sunscreen if swimming or sweating
- reapply 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.
 - use long-sleeved shirts, pants, hats, and sunglasses
 - children under 6 months. Ask a physician

Other Information

protect this product from excessive heat and direct sun

Inactive Ingredients

Water, Petrolatum, Isopropyl Palmitate, Ethylhexyl Stearate, Dimethicone, Triethylsiloxane, Glyceryl Stearate, PEG-10 Stearate, C12-13 Phosphatidyl Choline, Cetyl Alcohol, Cetyl Stearate, Hydroxyethyl Acrylate/Sodium Acrylate/Dimethyl Itaconate Copolymer, Polyacrylamide, Polysiloxane-1, Ethylhexylglycerin, PEG-7 Dimethylpropionate Coconut Ether, Citric Acid, Tocopheryl Acetate, Sodium Hyaluronate, Triethylhexylsilane

Questions or comments?

Call toll free 1-800-853-8872

PS0062993

EltaMD[®] UV Lotion Broad-Spectrum SPF 35 is a moisturizing sunscreen for the entire body. Use it every day to guard against sun damage and keep the skin hydrated. EltaMD UV Lotion is formulated with zinc oxide to protect skin from UVA (aging) and UVB (burning) rays and hyaluronic acid to help retain moisture. EltaMD UV Lotion is fragrance-free, paraben-free, non-comedogenic, and hypoallergenic.

Mtd. for CP Skin Health Group, Inc.
 Scottsdale, AZ 85251, USA
 1-800-853-8872 | eltamd.com

ELTAMD UV SPF35

octinoxate, zinc oxide sunscreen lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72043-6808 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 70 g in 1000 g |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 75 g in 1000 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) | |
| OCTYL STEARATE (UNII: 772Y4UFC8B) | |
| OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| CETEARYL GLUCOSIDE (UNII: 09FUA47KNA) | |
| GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| HYALURONIC ACID (UNII: S270N0TRQY) | |
| POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52) | |
| HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4) | |
| PEG-7 TRIMETHYLOLPROPANE COCONUT ETHER (UNII: MVJ3AD73GG) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:72043-6808-8 | 226 g in 1 TUBE; Type 0: Not a Combination Product | 05/31/2024 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 05/31/2024 | |

Labeler - CP Skin Health Group, Inc (611921669)

Registrant - Swiss-American CDMO, LLC (080170933)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|-------------------------|
| Swiss-American CDMO, LLC | | 080170933 | manufacture(72043-6808) |

Revised: 5/2024

CP Skin Health Group, Inc