

ELTAMD UV SHIELD SPF45- zinc oxide and octinoxate sunscreen lotion

EltaMD, 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.

EltaMD UV Shield SPF45

Warnings

For external use only Do not use on damaged or broken skin When using this product keep out of eyes 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.

Active Ingredients

Zinc Oxide 9.0% Sunscreen

Octinoxate 7.5% 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.

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. wear long-sleeve shirts, pants, hats and sunglasses children under 6 months: Ask a physician

Inactive Ingredients

Purified Water, Isopropyl Palmitate, Octyl Stearate, Cetearyl Alcohol, Polysorbate 60, Oleth-3 Phosphate, Phenoxyethanol, Cetearyl Glucoside, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyisobutene, Polyether-1, Butylene Glycol, PEG-7 Trimethylolpropane Coconut Ether, Tocopheryl Acetate, Citric Acid, Iodopropynyl Butylcarbamate, Triethoxycaprylylsilane

UVSHIELDUC

American Carton Company ACC 607 South Waterloo St. Marshall, Texas 78063 Phone: 817.477.1883 Fax: 817.478.0538		<input type="checkbox"/> UPC <input type="checkbox"/> PIC	<small>Please check all components of print (i.e. color, positioning, etc.), fill out proper information below, and return to American Carton Company. This form and any form of proof (i.e. rfx, rfx, baseline, rainbow, color key, etc.) must be returned to ACC before job will proceed any further.</small> DEVIATING RETURN OF PROOFS MAY DELAY DELIVERY OF YOUR JOB. <input checked="" type="checkbox"/> OK AS IS No responsibility for error is assumed by ACC when work is printed per customer's approval. <input type="checkbox"/> SHOW REVISED PROOF If revised proofs are required, request must be made when this proof is returned.
Customer: Swiss American Description: UVShield7ozBox080510D.pdf 1 11/1/16 8:33 AM CAD #: 080510D ACC Item #: SA0347 Date: 12-19-2016	Revision Number <input type="text" value="0"/>	<small>I hereby authorize American Carton Company to proceed as indicated by my choice above.</small> Carol Chapin Bocell Signature	<small>Digitally signed by Carol Chapin Bocell DN: cn=Carol Chapin Bocell, o=United American, ou=Marketing, serial=100, email=carol@americancc.com, c=US Date: 2016.12.19 10:56:48 -0500</small> Date

Supplies by suppliers

elta
MD

SKINCARE

A Swiss-American Company

UV SHIELD

BROAD-SPECTRUM
SPF 45 SUNSCREEN



elta
MD

SKINCARE

A Swiss-American Company

UV SHIELD

BROAD-SPECTRUM
SPF 45

LIGHTWEIGHT
TRANSPARENT ZINC OXIDE
UVA/UVB PROTECTION

FACE AND BODY SUNSCREEN

Oily to Normal Skin

OIL-FREE
net wt 7 oz / 198 g

SKINCARE

elta md
A Swiss-American Company

Drug Facts

Active Ingredients	Purpose
Zinc Oxide 9.0% } Octinoxate 7.5% }	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 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.
 - wear long-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a physician

Inactive ingredients

Purified Water, Isopropyl Palmitate, Octyl Stearate, Cetearyl Alcohol, Polyisobutene 60, Oleth-3 Phosphate, Phenoxethanol, Cetearyl Glucoside, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyisobutene, Polyether-1, Butylene Glycol, PEG-7 Trimethylolpropane Coconut Ether, Tocopheryl Acetate, Citric Acid, Iodopropynyl Butylcarbamate, Triethoxycaprylylsilane

Other information

- protect this product from excessive heat and direct sun

Questions or comments?
Call toll free 1-800-633-8872

Item # 02281

RM2195 Rev 11/16

EltaMD® UV Shield Broad-Spectrum SPF 45 sunscreen is a lightweight, oil-free formula that spreads easily and evenly across the skin. It blends in quickly with no residue, making it ideal for daily use under makeup or worn alone.

EltaMD UV Shield utilizes 9% micronized zinc oxide that is transparent on the skin. It provides broad-spectrum protection from UVA (aging) rays and provides an SPF 45 to protect from UVB (burning) rays. Developed for oily to normal skin, it can be used in conjunction with photosensitizing medications. Antioxidant protection combats skin-aging free radicals associated with ultraviolet (UV) and infrared radiation (IR).

EltaMD UV Shield is fragrance-free, oil-free, paraben-free, sensitivity-free and noncomedogenic.

Mfd. by Swiss-American
Carrollton, TX 75006
eltamd.com
Made in U.S.A.

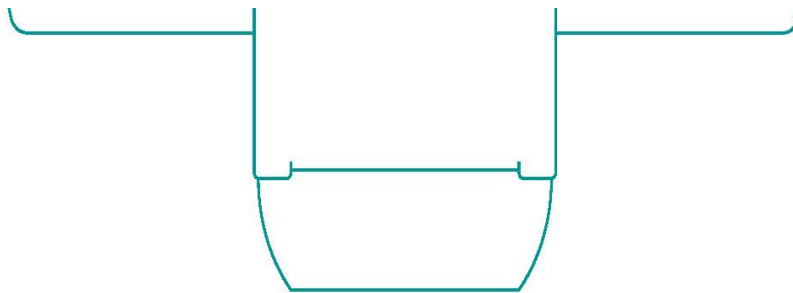


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The Skin Cancer Foundation recommends this product as an effective broad-spectrum sunscreen.



ELTAMD UV SHIELD SPF45

zinc oxide and octinoxate sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72043-2282
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	90 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)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
OCTYL STEARATE (UNII: 772Y4UFC8B)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (10000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	

POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72043-2282-3	85 g in 1 TUBE; Type 0: Not a Combination Product	01/10/2018	
2	NDC:72043-2282-8	198 g in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/10/2018	

Labeler - EltaMD, Inc. (611921669)

Registrant - Swiss-American CDMO, LLC (080170933)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(72043-2282)

Revised: 10/2018

EltaMD, Inc.