

ELTAMD UV RESTORE- titanium dioxide, zinc oxide sunscreen lotion
CP Skin Health Group, Inc

EltAMD UV Restore

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

Titanium Dioxide 2.0% Sunscreen
Zinc Oxide 15.0% Sunscreen

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.

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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

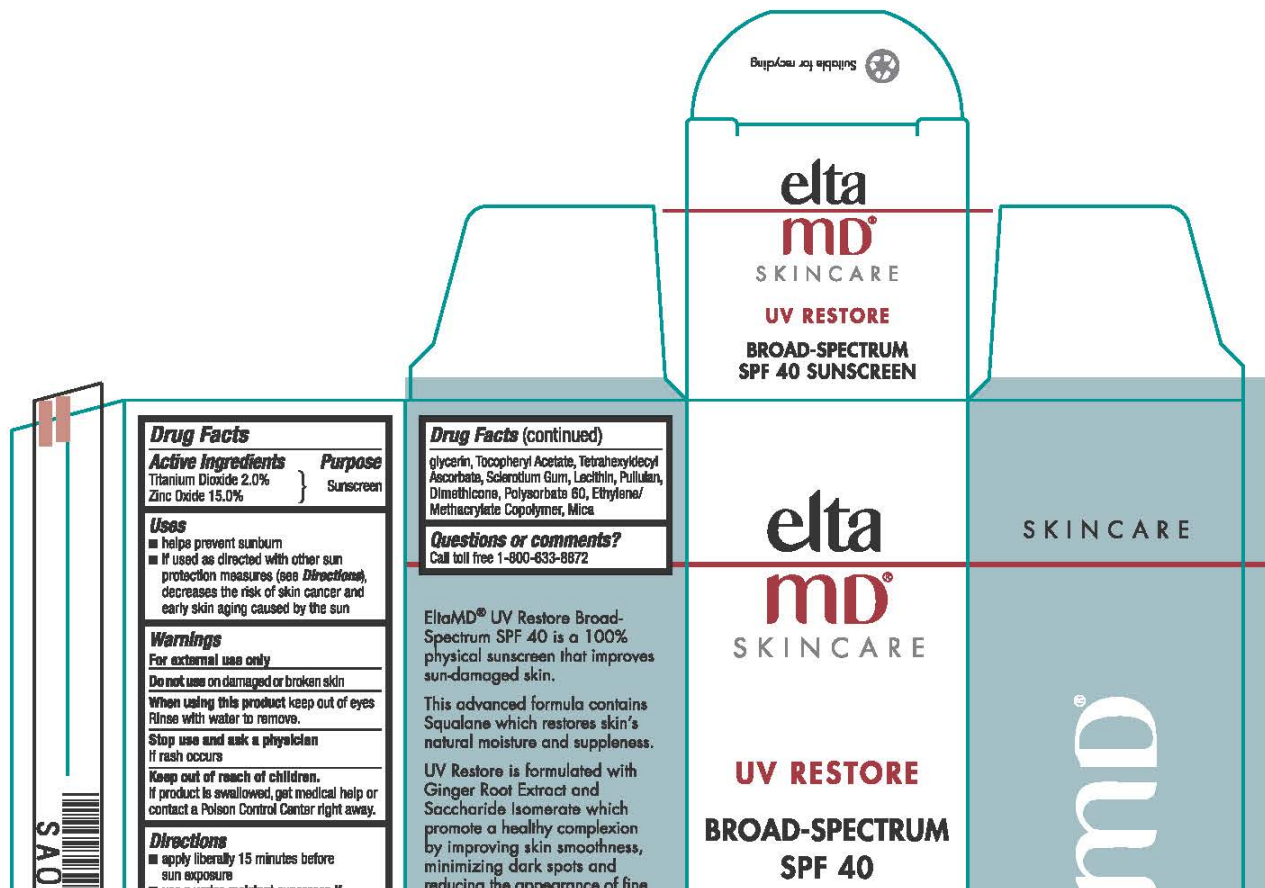
water, coco-caprylate/caprate, butyloctyl salicylate, octyldodecyl neopentanoate, caprylic/capric triglyceride, methyl glucose sesquistearate, silica, glyceryl stearate, PEG-100 stearate, PEG-20 methyl glycoses sesquisterate, phenoxyethanol, triethoxycaprylylsilane, polyhydroxystearic acid, glycerin, saccharide isomerate, glyceryl behenate, xanthan gum, zingiber officiale (ginger) root extract, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, squalene, ethylhexylglycerin, tocopheryl acetate, sclerotium gum, lecithin, pullulan, dimethicone, polysorbate 60, ethylene/methacrylate copolymer, mica

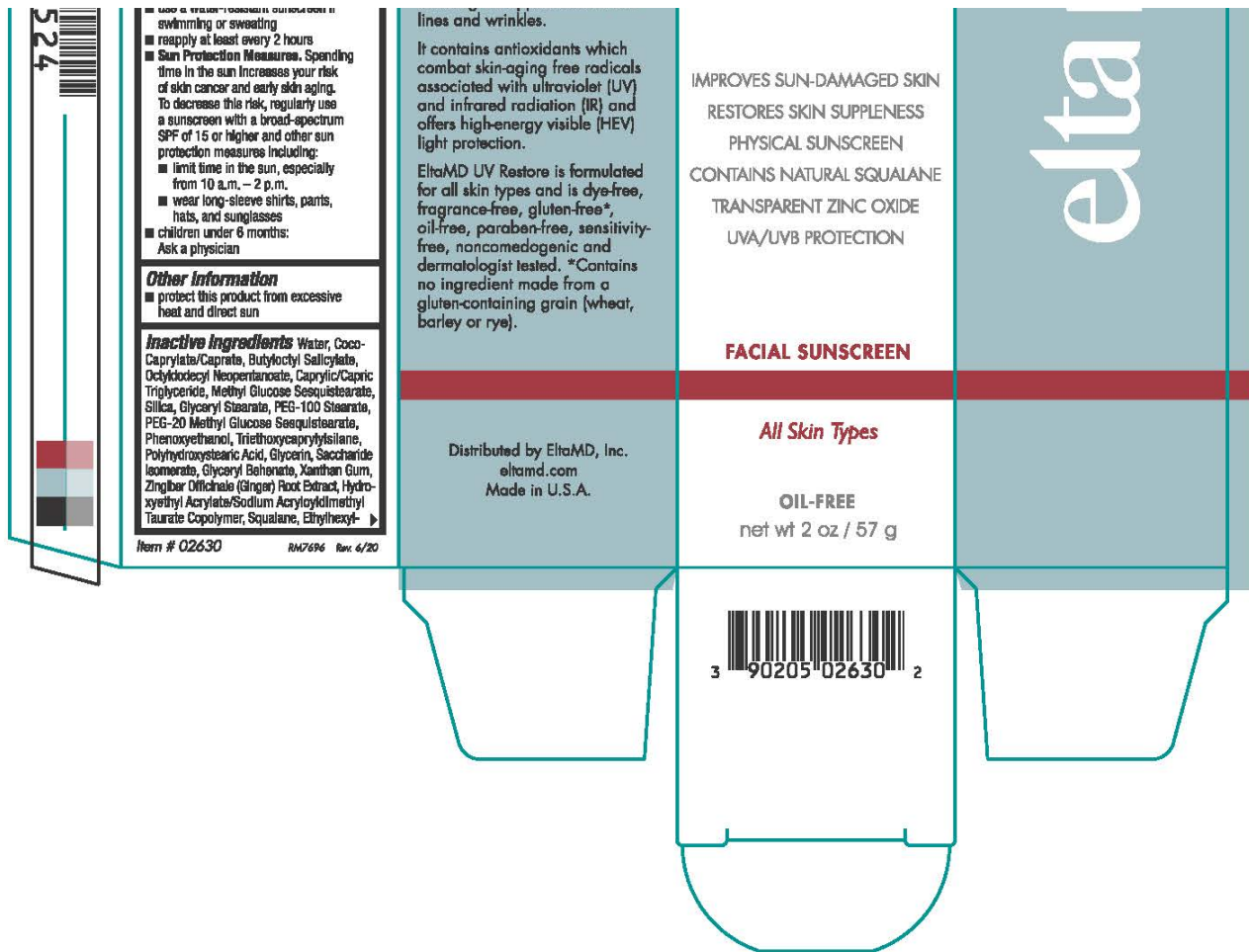
Questions

Call toll free 1-800-633-8872

Labeling

American Carton Company  907 South Wisteria St. Mansfield, Texas 76063 Phone: 817.477.1963 Fax: 817.473.0633	 ACC DIE	 201	 7542	 Black	 UPC	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. mylar, blue-line, rainbow, color key, etc.) must be returned to ACC before job will proceed any further.
Customer: Swiss American Description: UV Restore Carton-C3920_RM7696.pdf 1 6/23/20 12:24 PM CAD #: A6193_SBS ACC Item #: SA0524 Date: 6-30-2020					 PIC	DELAYING RETURN OF PROOFS MAY DELAY DELIVERY OF YOUR JOB. <input 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.
Revision Number <div style="border: 1px solid black; padding: 2px; display: inline-block;">0</div>					I hereby authorize American Carton Company to process as indicated by my choice above.	
Proof Output Date					Signature	Date





ELTAMD UV RESTORE

titanium dioxide, zinc oxide sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72043-2630
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	20 g in 1000 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	150 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
WATER (UNII: 059QF0K00R)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
METHYL GLUCOSE SESQUISTEARATE (UNII: V1YW10H14D)	
PEG-20 METHYL GLUCOSE SESQUISTEARATE (UNII: 0345752X7U)	
GLYCERIN (UNII: PDC6A3C00X)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
MICA (UNII: V8A1AW0880)	
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KBJ1I)	
GINGER (UNII: C5529G5JPQ)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72043-2630-4	2 g in 1 PACKET; Type 0: Not a Combination Product	10/01/2020	

2	NDC:72043-2630-2	57 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2020	
3	NDC:72043-2630-5	14 g in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	
4	NDC:72043-2630-1	48 g in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/01/2020	

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(72043-2630)

Revised: 11/2023

CP Skin Health Group, Inc