ELTAMD UV ACTIVE- zinc oxide, titanium dioxide sunscreen cream CP Skin Health Group, Inc.

EltaMD UV Active

Warnings

For external use only. Do not use on damaged or broken skin. Stop use and ask physician if rash occurs. When using this product keep out of eyes. Rinse with water to remove. If product is swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children.

Keep out of reach of children.

Active Ingredients

Zinc Oxide 19.0% Sunscreen

Titanium Dioxide 4.0% Sunscreen

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.

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. Reapply after 80 minutes of swimming or sweating, immediately after towel drying, at least every two 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 sunscreen with a broad-spectrum SPF value of 15 or higher. Limit time in the sun, especially from 10 am to 2 pm. Wear long sleeved shirts, pants, hats and sunglasses. Before use on children under 6 months, ask a physician.

Questions

Questions or Comments?

1-800-633-8872

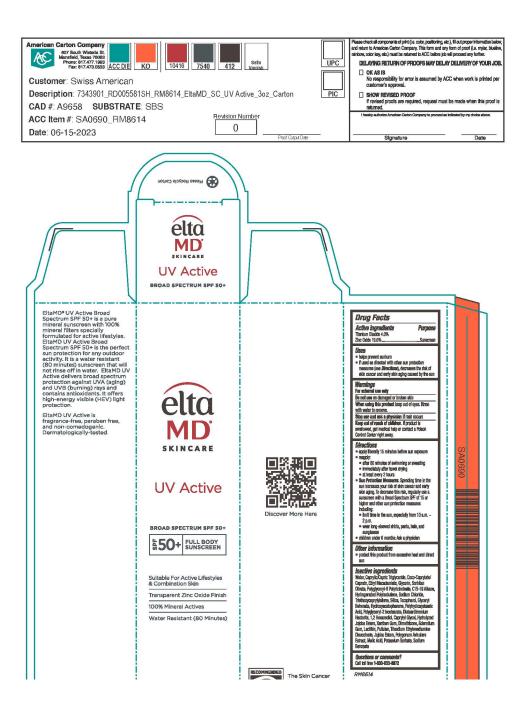
Other information

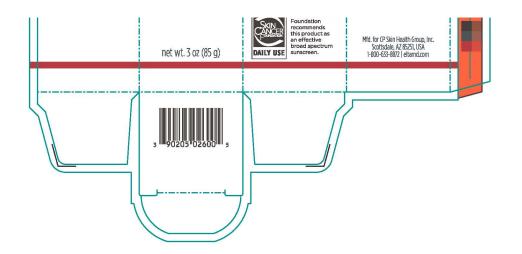
Protect this product from excessive heat and direct sun.

Inactive ingredients

water, caprylic/capric trigylceride, coco-caprylate/caprate, ethyl macadamiate, glycerin, sorbitan olivate, polyglyceryl-6 polyricinoleate, C15-19 alkane, hydrogenated polyisobutene, sodium chloride, triethoxycaprylylsilane, silica, glyceryl beheanate, hydroxyacetophenone, polyglyceryl-2 isostearate, polyhydroxysearic acid, disteardimonium hectorite, 1,2-hexanediol, caprylyl glycol, hydrolyzed jojoba esters, xanthan gum, diemthicone, sclerotium gum, trisodium ethylenediamine disuccinate, lecithin, pullulan, jojoba esters, polygonum aviculare extract, tocopherol, malic acid

Labeling





ELTAMD UV ACTIVE				
zinc oxide, titanium dioxide s	unscreen cream			
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (S	Source) NE	DC:72043-2600
Route of Administration	TOPICAL			
Active Ingredient/Active	Moiety			
-	dient Name		Basis of Streng	th Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) ZINC CATION				
	ZINC CATION - UNII:13515	85F37)	ZINC CATION	190 g in 1000
TITANIUM DIOXIDE (UNII: 15FIX9)			TITANIUM DIOXIDE	40 g in 1000 g
				-
TITANIUM DIOXIDE (UNII: 15FIX9)		JNII:15FIX9V2JP)		-
TITANIUM DIOXIDE (UNII: 15FIX9) Inactive Ingredients WATER (UNII: 059QF0K00R)	V2JP) (TITANIUM DIOXIDE - U Ingredient Name	JNII:15FIX9V2JP)		40 g in 1000 g
TITANIUM DIOXIDE (UNII: 15FIX9) Inactive Ingredients WATER (UNII: 059QF0K00R) SODIUM CHLORIDE (UNII: 451W4	V2JP) (TITANIUM DIOXIDE - U Ingredient Name 7IQ8X)	JNII:15FIX9V2JP)		40 g in 1000 g
TITANIUM DIOXIDE (UNII: 15FIX9) Inactive Ingredients WATER (UNII: 059QF0K00R) SODIUM CHLORIDE (UNII: 451W4 XANTHAN GUM (UNII: TTV12P4NE	V2JP) (TITANIUM DIOXIDE - U Ingredient Name 7IQ8X) E)	JNII:15FIX9V2JP)		40 g in 1000 g
TITANIUM DIOXIDE (UNII: 15FIX9) Inactive Ingredients WATER (UNII: 059QF0K00R) SODIUM CHLORIDE (UNII: 451W4 XANTHAN GUM (UNII: TTV12P4NE LECITHIN, SOYBEAN (UNII: 1DI56	V2JP) (TITANIUM DIOXIDE - U Ingredient Name 7IQ8X) E)	JNII:15FIX9V2JP)		40 g in 1000 g
TITANIUM DIOXIDE (UNII: 15FIX9) Inactive Ingredients WATER (UNII: 059QF0K00R) SODIUM CHLORIDE (UNII: 451W4 XANTHAN GUM (UNII: TTV12P4NE LECITHIN, SOYBEAN (UNII: 1DI56 PULLULAN (UNII: 8ZQ0AYU1TT)	V2JP) (TITANIUM DIOXIDE - U Ingredient Name 7IQ8X) E) SQDM62)	JNII:15FIX9V2JP)		40 g in 1000 g
TITANIUM DIOXIDE (UNII: 15FIX9) Inactive Ingredients WATER (UNII: 059QF0K00R) SODIUM CHLORIDE (UNII: 451W4 XANTHAN GUM (UNII: TTV12P4NE LECITHIN, SOYBEAN (UNII: 1DI56 PULLULAN (UNII: 8ZQ0AYU1TT) ALUMINUM SILICATE (UNII: T1FA	V2JP) (TITANIUM DIOXIDE - U Ingredient Name 7IQ8X) E) 5QDM62) D4SS2M)	JNII:15FIX9V2JP)		40 g in 1000 g
TITANIUM DIOXIDE (UNII: 15FIX9) Inactive Ingredients WATER (UNII: 059QF0K00R) SODIUM CHLORIDE (UNII: 451W4 XANTHAN GUM (UNII: TTV12P4NE LECITHIN, SOYBEAN (UNII: 1DI56 PULLULAN (UNII: 8ZQ0AYU1TT)	V2JP) (TITANIUM DIOXIDE - U Ingredient Name 7IQ8X) E) 5QDM62) D4SS2M) DISUCCINATE (UNII: YA22	JNII:15FIX9V2JP)		40 g in 1000 g
TITANIUM DIOXIDE (UNII: 15FIX9) Inactive Ingredients WATER (UNII: 059QF0K00R) SODIUM CHLORIDE (UNII: 451W4 XANTHAN GUM (UNII: TTV12P4NE LECITHIN, SOYBEAN (UNII: 1DI56 PULLULAN (UNII: 8ZQ0AYU1TT) ALUMINUM SILICATE (UNII: T1FA TRISODIUM ETHYLENEDIAMINE	V2JP) (TITANIUM DIOXIDE - U Ingredient Name 7IQ8X) E) 5QDM62) D4SS2M) DISUCCINATE (UNII: YA22	JNII:15FIX9V2JP)		40 g in 1000 g
TITANIUM DIOXIDE (UNII: 15FIX9) Inactive Ingredients WATER (UNII: 059QF0K00R) SODIUM CHLORIDE (UNII: 451W4 XANTHAN GUM (UNII: TTV12P4NE LECITHIN, SOYBEAN (UNII: 1DI56 PULLULAN (UNII: 8ZQ0AYU1TT) ALUMINUM SILICATE (UNII: T1FA TRISODIUM ETHYLENEDIAMINE HYDROXYACETOPHENONE (UNII	V2JP) (TITANIUM DIOXIDE - U Ingredient Name 7IQ8X) E) 5QDM62) D4SS2M) DISUCCINATE (UNII: YA22 : G1L3HT4CMH)	JNII:15FIX9V2JP)		40 g in 1000 g
TITANIUM DIOXIDE (UNII: 15FIX9) Inactive Ingredients WATER (UNII: 059QF0K00R) SODIUM CHLORIDE (UNII: 451W4 XANTHAN GUM (UNII: TTV12P4NE LECITHIN, SOYBEAN (UNII: 1DI56 PULLULAN (UNII: 8ZQ0AYU1TT) ALUMINUM SILICATE (UNII: T1FA TRISODIUM ETHYLENEDIAMINE HYDROXYACETOPHENONE (UNII glycerin (UNII: PDC6A3C00X)	V2JP) (TITANIUM DIOXIDE - U Ingredient Name 7IQ8X) E) 5QDM62) D4SS2M) DISUCCINATE (UNII: YA22 : G1L3HT4CMH)	JNII:15FIX9V2JP)		40 g in 1000 g

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
C15-19 ALKANE (UNII: CI87N1IM01)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
ETHYLHEXYLGLYCERYL BEHENATE (UNII: JRY34LRD7B)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
POLYGLYCERYL-2 ISOSTEARATE (UNII: 7B80E71MQC)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	

Product Characteristics

Color	white	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72043- 2600-3	90 g in 1 TUBE; Type 0: Not a Combination Product	02/03/2020	
2	NDC:72043- 2600-2	2 g in 1 PACKET; Type 0: Not a Combination Product	08/24/2021	
3	NDC:72043- 2600-8	234 g in 1 TUBE; Type 0: Not a Combination Product	07/06/2022	11/09/2023

Marketing Information				
Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date				
OTC Monograph Drug	M020	02/03/2020		

Labeler - CP Skin Health Group, Inc. (611921669)

Registrant - Swiss-American CDMO, LLC (080170933)

Establishment					
Name	Address	ID/FEI	Business Operations		
CP Skin Health Group, Inc.		080170933	manufacture(72043-2600)		

Revised: 11/2023