

**CORALSAFE BROAD SPECTRUM SPF30- titanium dioxide, zinc oxide cream
Elements Brands**

CoralSafe Broad Spectrum SPF30

DRUG FACTS

Active Ingredients

Titanium Dioxide (6.0%)

Zinc Oxide (6.0%)

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 or irritation 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 80 minutes of swimming or sweating • Immediately after towel drying • At least every 2 hours • 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: **Sun Protection Measures:**

- Limiting time in the sun, especially from 10 am - 2 pm.
- Wearing long-sleeve shirts, pants, hats and sunglasses
- Children under 6 months: Ask a doctor

Inactive Ingredients:

Aloe Barbadensis (Aloe Vera) Juice, Aqua (Deionized Water), Butyrospermum Parkii (Shea) Butter, Camellia Sinensis (Green Tea) Extract, Cocos Nucifera (Coconut) Oil, Dehydroxanthan Gum, Gluconolactone, Glycerin, Glycine Soja (Soybean) Oil, Helianthus Annuus (Sunflower) Oil, Lecithin, Mangifera Indica (Mango) Butter, Sodium Benzoate, Sodium Laurylglucosides Hydroxypropylsulfonate, Styrene/Acrylates Copolymer, Tocopheryl (Vitamin-E), Xanthan Gum.

Other Information:

Protect this product from excessive heat and direct sun.

Package Labeling:

Apply 15 minutes before sun exposure (a little goes a long way).

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CORALS SAFE BROAD SPECTRUM SPF30

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71221-333
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	60 mg in 1 L
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	60 mg in 1 L

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	
SHEA BUTTER (UNII: K49155WL9Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DEHYDROXANTHAN GUM (UNII: 63ZP7I1BQO)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
GLYCERIN (UNII: PDC6A3C0OX)	
SOYBEAN OIL (UNII: 241ATL177A)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
MANGO (UNII: I629I3NR86)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71221-333-00	1 in 1 CARTON	06/01/2018	
1		3.78 L in 1 JUG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/01/2018	

Labeler - Elements Brands (006166707)

Revised: 11/2023

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