

SUNSCREEN COLOR BROAD SPECTRUM SPF 50- titanium dioxide, zinc oxide gel
CryoGen, LLC

Sunscreen Gel Color Broad spectrum SPF 50+

Drug Facts

Active ingredients

Titanium Dioxide 10%

Zinc Oxide 5%

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 occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally and evenly 15 minutes before sun exposure
- apply to all skin exposed to the sun
- reapply at least every 2 hours

- use a water resistant sunscreen if swimming or sweating
- children under 6 months of age: Ask a doctor
- **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 value 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-sleeved shirts, pants, hats and sunglasses

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

Water, Human Umbilical Mesenchymal Stem Cell Exosomes, Oat (Avena sativa) Extract, Stearic Acid, Sorbitan Stearate, Glycerin, Iron Oxide, Hydroxyacetophenone, Fragrance

Package Labeling:



SUNSCREEN COLOR BROAD SPECTRUM SPF 50

titanium dioxide, zinc oxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83802-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	100 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
OAT (UNII: Z6J799EAJK)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
GLYCERIN (UNII: PDC6A3C0OX)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83802-001-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/01/2023	

Labeler - CryoGen, LLC (127842726)

Revised: 11/2023

CryoGen, LLC