

SUNSCREEN BROAD SPECTRUM SPF 30- titanium dioxide, zinc oxide lotion
Capsule Corporation

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.

Sunscreen lotion Broad Spectrum SPF 30

Drug Facts

Active Ingredient

Titanium Dioxide 6.00%

Zinc Oxide 6.00%

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 consult physician

- if irritation or rash develops.

Keep out of reach of children

- if product is swallowed, get medical attention or contact poison control center immediately.

Directions

- Apply liberally 15-minutes before sun exposure.
- Reapply:
- At least, every 2 hours.
- Immediately after swimming, sweating or towel drying.
- 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 broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including:
- Limit time in the sun, especially between 10am and 2pm.

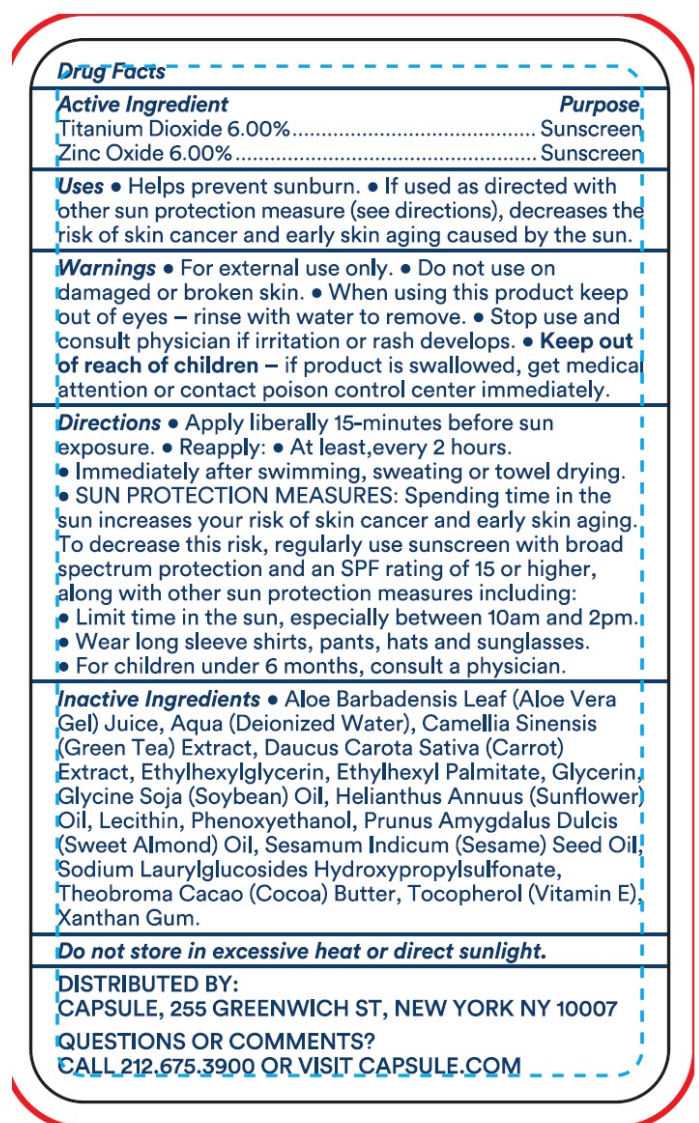
- Wear long sleeve shirts, pants, hats and sunglasses.
- For children under 6 months, consult a physician.

Inactive Ingredients

- Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Camellia Sinensis (Green Tea) Extract, Daucus Carota Sativa (Carrot) Extract, Ethylhexylglycerin, Ethylhexyl Palmitate, Glycerin, Glycine Soja (Soybean) Oil, Helianthus Annuus (Sunflower) Oil, Lecithin, Phenoxyethanol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sesamum Indicum (Sesame) Seed Oil, Sodium Laurylglucosides Hydroxypropylsulfonate, Theobroma Cacao (Cocoa) Butter, Tocopherol (Vitamin E) Xanthan Gum.

Do not store in excessive heat or direct sunlight.

Package Labeling:



SUNSCREEN BROAD SPECTRUM SPF 30

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70469-142	
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 mL	
	ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	60 mg in 1 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	ALOE VERA LEAF (UNII: ZY81Z83H0X)			
	WATER (UNII: 059QF0KO0R)			
	GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
	CARROT (UNII: L56Z1JK48B)			
	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
	ETHYLHEXYL PALMITATE (UNII: 2865993309)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	SOYBEAN OIL (UNII: 241ATL177A)			
	HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)			
	PHENOXYETHANOL (UNII: HIE492ZZ3T)			
	ALMOND OIL (UNII: 66YXD4DKO9)			
	SESAME OIL (UNII: QX10HYY4QV)			
	COCOA (UNII: D9108TZ9KG)			
	TOCOPHEROL (UNII: R0ZB2556P8)			
	XANTHAN GUM (UNII: TTV12P4NEE)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70469-142-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2020	
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC monograph not final	part352	05/25/2020	

Labeler - Capsule Corporation (079920193)

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Capsule Corporation