

BIGGREEN EVERYDAY SUN- titanium dioxide, zinc oxide cream
BIGGREEN INC.

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.

Drug Facts

Titanium Dioxide, Zinc Oxide

Water, Dicaprylyl Carbonate, Polyglyceryl-3 Diisostearate, Glycerin, Polyglyceryl-2 Dipolyhydroxystearate, Stearic Acid, Aluminum Hydroxide, Helianthus Annuus (Sunflower) Seed Oil, Centella Asiatica Extract, Mangifera Indica (Mango) Seed Butter, Cocos Nucifera (Coconut) Oil, Hippophae Rhamnoides Seed Oil, Rosa Canina Fruit Extract, Zanthoxylum Piperitum Fruit Extract, Pulsatilla Koreana Extract, Usnea Barbata (Lichen) Extract, Lactobacillus/Hibiscus Sabdariffa Flower Ferment Filtrate, Voacanga Africana Seed Extract, Distarch Phosphate, Sodium Chloride, Glyceryl Caprylate, Silica, 1,2-Hexanediol, Ethyl Ferulate, Hydrolyzed Jojoba Esters, Geranium Maculatum Oil

Skin Protectant - Sun Block

keep out or reach of the children

- Apply liberally 15 minutes before sun exposure.
- Children under 6 months ask a doctor.
- Reapply after water activity.

1. Do not use in the following cases(Eczema and scalp wounds)

2.Side Effects

1)Due to the use of this drug if rash, irritation, itching and symptoms of hypersensitivity occur discontinue use and consult your pharmacist or doctor

3.General Precautions

1)If in contact with the eyes, wash out thoroughly with water If the symptoms are severe, seek medical advice immediately

2)This product is for external use only. Do not use for internal use

4.Storage and handling precautions

1)If possible, avoid direct sunlight and store in cool and area of low humidity

2)In order to maintain the quality of the product and avoid misuse

3)Avoid placing the product near fire and store out in reach of children

for external use only



BIGGREEN EVERYDAY SUN

titanium dioxide, zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:71251-0001

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	11.25 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.85 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71251-0001-1	50 g in 1 TUBE; Type 0: Not a Combination Product	02/20/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/20/2017	

Labeler - BIGGREEN INC. (694492118)**Registrant** - BIGGREEN INC. (694492118)**Establishment**

Name	Address	ID/FEI	Business Operations
Clagen Co., Ltd.		690053673	manufacture(71251-0001)

Establishment

Name	Address	ID/FEI	Business Operations
BIGGREEN INC.		694492118	label(71251-0001) , pack(71251-0001)

Revised: 5/2018

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