FHF ELEVATED SHADE 100% MINERAL SUNSCREEN- sunscreen lotion Owen Biosciences 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.

Owen Biosciences FHF Elevated Shade SPF 30

Active Ingredient

7 inc Oxide

Purpose

Sunscreen

Uses

Helps prevent sunburn Provides moderate protection against sunburn

Warnings

Do not use on broken or damaged skin When using this product keep out of eyes. Rinse with water to remove. Stop use and ask docctor if rash occurs Keep out of reach of children. If swallowed, get medical help or contact Poison Control.

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Directions

Apply generously and evenly 15 minutes before sun exposure 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 decreasse 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 especialy from 10a.m. - 2 p.m. Wear long-sleeve shirts, pants, hats, and sunglasses Reapply at least every 2 hours Use a water-resistant sunscreen if swimming or sweating

Other Information

Protect the product in this container from excessive heat and direct sun

Inactive Ingredients

Water, Caprylic/Capric Triglyceride, Ethyl Macadamiate, Glycerin, Propanediol, Polyglyceryl-3 Polyricinoleate, Triethoxycaprylylsilane, Polyglyceryl-10 Stearate, Cetearyl Olivate, Xanthan Gum, Magnesium Aluminum Silicate, Sodium Hyaluronate, Sodium PCA, Niacinamide, Allantoin, Quercitin, Sodium Ascorbyl Phosphate, Camellia Sinensis Leaf Extract, Sodium Chloride, Glyceryl Isostearate, Polyhydroxystearic, Sorbitan Olivate, Linum Usitatissimum (Linseed) Seed Oil, Tocopherol, Iron Oxides, Triethoxysilylpropyl Acetyl Hydroxyprolinate, Phenoxyethanol, Caprylyl Glycol, Polymethyl Methacrylate, Tromethamine, Pisum Sativum (Dwarf Grey Sugar Pea) Extract, Parfum

Package Label



FHF ELEVATED SHADE 100% MINERAL SUNSCREEN

sunscreen lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59958-601	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.21 g in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

l	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:59958-601- 01	50 g in 1 BOTTLE; Type 0: Not a Combination Product	03/21/2022	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	03/21/2022		

Labeler - Owen Biosciences Inc (790003045)

Establishment				
Name	Address	ID/FEI	Business Operations	
Owen Biosciences Inc		790003045	manufacture(59958-601)	

Revised: 3/2022 Owen Biosciences Inc