

SKINFUSE SHIELD SPF 30- zinc oxide cream
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.

Skinfuse Shield 60g

Drug Facts

label

SKINFUSE
SHIELD
 Zinc Oxide
 21%
 SPF 30
 Sunscreen

2fl oz/60mL

DRUG FACTS

Active Ingredients	Purpose
Zinc Oxide 21%, SPF 30	Sunscreen

Uses
 Helps protect against sunburn.

Warnings
For external use only. Do not use on damaged or broken skin. Stop use and ask doctor if rash and irritation develops and lasts.
Avoid contact with eyes. If product gets into eyes, rinse thoroughly with water.
Keep out of reach of children. If swallowed, get medical help or contact poison control center right away.

Directions

- Evenly apply to skin before exposure to sun and as needed.
- Children under 6 months, ask doctor.
- Protect this product from excessive heat and direct sun.

Inactive Ingredients
 Water (Aqua), Simmondsia Chinensis (Jojoba) Seed Oil, Glycerol Isostearate, Coconut Alkanes, Coco-Caprylate/Caprates, Ethyl Macadamiate, Glycerin, Propanediol, Polyglyceryl-3 Polynicotinate, Cetearyl Olivat, Sorbitan Olivat, Caprylic/Capric Triglyceride, Cocoglycerides, p-Anisic acid, Argania Spinosa Kernel Oil, Tocopherol Linoleate / Oleate, Lysolecithin, Polyglyceryl-3 Stearate, Neopentyl Glycol Diethylhexanoate, Glycerol Caprylate, Glycerol Undecylenate, Copernicia Cerifera (Carnauba) Wax, Cetearyl Alcohol, Cetearyl Glucoside, Xanthan Gum, Sodium Chloride, Iron Oxides, Polyhydroxystearic Acid, Triethoxycaprylylsilane.

Distributed Exclusively by Bellus Medical, LLC, Dallas, Texas 75243 USA 1-888-372-3982

SKINFUSE SHIELD SPF 30			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59958-240
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	21 g in 100 g	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0K00R)		34 g in 100 g		
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)		5 g in 100 g		
GLYCERIN (UNII: PDC6A3C00X)		5 g in 100 g		
PROPANEDIOL (UNII: 5965N8W85T)		5 g in 100 g		
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)		4 g in 100 g		
JOJOBA OIL (UNII: 724GKU717M)		8.97 g in 100 g		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59958-240-02	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/17/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	11/17/2015		

Labeler - Owen Biosciences, Inc. (790003045)

Establishment

Name	Address	ID/FEI	Business Operations
Owen Biosciences, Inc.		790003045	manufacture(59958-240)

Revised: 1/2023

Owen Biosciences, Inc.