

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 30g

label

SKINFUSE[®]



SHIELD
Zinc Oxide
21%

SPF 30
Sunscreen

1/30mL

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.

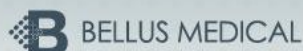
Avoid contact with eyes If product gets into eyes, rinse thoroughly with water.

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, Glyceryl Isostearate, Coconut Alkanes, Coco-Caprylate/Caprates, Ethyl Macadamiate, Glycerin, Propanediol, Polyglyceryl-3 Polyricinoleate, Cetearyl Oliviate, Sorbitan Oliviate, Caprylic/Capric Triglyceride, Caprylyl Methicone, Cocoglycerides, p-Anisic acid, Argania Spinosa Kernel Oil, Tocopherol Linoleate / Oleate, Lysolecithin, Polyglyceryl-3 Stearate, Neopentyl Glycol, Diethylhexanoate, Glyceryl Caprylate, Glyceryl 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
www.skinfuse.com
1-888-372-3982

SKINFUSE SHIELD SPF 30

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59958-240
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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: 059QF0KO0R)	34 g in 100 g
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	5 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	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:59958-240-01	30 g in 1 TUBE; Type 0: Not a Combination Product	11/12/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/11/2015	

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.