

ANHYDROUS SPF 30- titanium dioxide, 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.

Owen Biosciences Anhydrous SPF 30 30 g tube

Drug Facts

Active ingredients	Purpose
Titanium Dioxide 10.20%	Sunscreen
Zinc Oxide 3.70%	Sunscreen

USES

Helps Prevent sunburn.
Higher SPF gives more sunburn protection
Provides moderate protection against sunburn.

Warnings

For external use only. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask doctor if rash and irritation develops and lasts. Keep out of reach of children. If swallowed, get medical help or contact poison control center right away.

Directions

Apply evenly before sun exposure and as needed. For children under 6 months of age: ask a doctor. Reapply as needed or after towel drying, swimming or perspiring.

Other Information

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin cancer, and other harmful effects of the sun.

Inactive Ingredients

Cyclopentasiloxane, Cyclomethicone, Dimethicone Crosspolymer, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer,

Dimethicone/Vinyl Dimethicone Crosspolymer, Melanin, Tribehenin, Calcium Behenate, Sorbitan Isostearate, Dimethiconol,

Alumina, PEG-10 Dimethicone, Methicone, Iron Oxides.



Dermaroller®

SUN SCREEN SPF 30

e 30 ml - 1 fl. oz.

Drug Facts	
Active Ingredients	Purpose
Titanium dioxide 10.20 %	Sunscreen
Zinc oxide 3.70 %	Sunscreen
Use	
<ul style="list-style-type: none"> • helps prevent sunburn 	
Warnings	
<p>Skin Cancer / Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.</p> <p>For external use only.</p> <p>Do not use on damaged or broken skin.</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs.</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p>	
Directions	
<ul style="list-style-type: none"> • apply liberally 15 minutes before sun exposure • use a water resistant sunscreen if swimming or sweating • reapply at least every 2 hours • children under 6 months: Ask a doctor 	
Inactive Ingredients	
Alumina, Calcium Behenate, Cyclomethicone, Cyclopentasiloxane, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxides, Melanin, Methicone, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer, PEG-10 Dimethicone, Sorbitan Isostearate, Tribehenin	
Other information	
<ul style="list-style-type: none"> • protect this product from excessive heat and direct sun • Made in USA by Owen Biosciences Inc. exclusively for Dermalroller GmbH 	

ANHYDROUS SPF 30

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59958-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	10.2 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	17.5 g in 100 g
TRIBEHENIN (UNII: 8OC9U7TQZ0)	1 g in 100 g
FERRIC OXIDE RED (UNII: 1K09F3G675)	0.09 g in 100 g
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	0.25 g in 100 g
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	0.01 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59958-200-03	30 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2011	

Labeler - Owen Biosciences, Inc. (790003045)

Registrant - Owen Biosciences, Inc. (790003045)

Establishment

Name	Address	ID/FEI	Business Operations
Owen Biosciences, Inc.		790003045	manufacture(59958-200)