

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 Drug Facts Anhydrous SPF 30

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.

<p>Active Ingredients</p> <table border="0"> <tr> <td>Titanium Dioxide</td> <td>10.20%</td> <td>Sunscreen</td> </tr> <tr> <td>Zinc Oxide</td> <td>3.70%</td> <td>Sunscreen</td> </tr> </table> <p>Uses Helps prevent sunburn Higher SPF gives more sunburn protection Provides moderate protection against sunburn</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p style="text-align: center;">Manufactured for: The Center for Dermatology 4310 Old Shell Rd. - Suite D Mobile, AL 36608 www.ponceskincares.com</p>	Titanium Dioxide	10.20%	Sunscreen	Zinc Oxide	3.70%	Sunscreen	 <p>PONCÉ™</p> <p>ANHYDROUS BLOCK SPF 30</p> <p><i>tinted block</i></p> <p>Dena J. Howell, MD Amy M. Morris, MD</p> <p>2 oz (60 ml)</p>
Titanium Dioxide	10.20%	Sunscreen					
Zinc Oxide	3.70%	Sunscreen					

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)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59958-200-01	100000 g in 1 DRUM; 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 final	part352	09/01/2009	

Labeler - Owen Biosciences, Inc. (790003045)

Revised: 4/2022

Owen Biosciences, Inc.