

FACIAL MINERAL SUNSCREEN NON TINTED- titanium dioxide, zinc oxide cream
DR. CARIN GRIBETZ BOARD CERTIFIED DERMATOLOGIST

DRUG FACTS

ACTIVE INGREDIENTS: Titanium Dioxide 8
Zinc Oxide 3.8%

PURPOSE: Sunscreen
Sunscreen

USES:
Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

WARNINGS:
For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:
• Apply liberally 15 minutes before sun exposure.
• Reapply:
• After 80 minutes of swimming or sweating
• Immediately after towel drying
• At least every 2 hours
• Children under 6 months: Ask a doctor
• **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease 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, especially from 10 am-2 pm
• Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:
Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

OTHER INFORMATION:
• Protect this product from excessive heat and direct sun
• PA ++++

MANUFACTURED FOR:
Carin Gribetz, M.D., P.C
New York, NY 10028
(212) 289 - 3300



Facial
Mineral
Sunscreen
Non-Tinted

Broad Spectrum
SPF 40
Water Resistant
(80 minutes)

Net Wt. 1.8 oz / 53 g

FACIAL MINERAL SUNSCREEN NON TINTED

titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85634-202(NDC:58892-202)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	38 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	80 mg in 1 g

Inactive Ingredients				
Ingredient Name			Strength	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)				
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)				
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
ALUMINA (UNII: LMI26O6933)				
CYCLOHEXASILOXANE (UNII: XHK3U310BA)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85634-202-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/11/2023	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M020	04/11/2023	

Labeler - DR. CARIN GRIBETZ BOARD CERTIFIED DERMATOLOGIST (123102195)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85634-202)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85634-202)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85634-202)

Revised: 12/2025

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