

MINERAL SUNSCREEN MOISTURIZING NON-TINTED- zinc oxide cream
Cutis Wellness Dermatology And Dermatopathology PLLC

DRUG FACTS


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:
Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer


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

MANUFACTURED FOR:
DermLayer by Cutis
Wellness Dermatology
Laredo, TX 78041



**Mineral Sunscreen
Moisturizing
Non-Tinted**

Broad Spectrum SPF 40
Zinc Oxide



Gentle on all skin types
Contains ceramides
and antioxidants C & E

- Reef Friendly
- Non-Comedogenic
- Paraben Free

DRUG FACTS

ACTIVE INGREDIENTS: PURPOSE:
Zinc Oxide 16% 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.
• Use a water resistant product if swimming or sweating.
• Reapply at least every 2 hours
• Children under 6 months: Ask a doctor



“Made with you in mind”

www.cutiswellnessderm.com

Net Wt. 1.75 oz / 50 g

(956) 608-3071

MINERAL SUNSCREEN MOISTURIZING NON-TINTED zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85431-226(NDC:58892-226)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	160 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CERAMIDE 3 (UNII: 4370DF050B)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85431-226-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/20/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/20/2023	

Labeler - Cutis Wellness Dermatology And Dermatopathology PLLC (066954385)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85431-226)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85431-226)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85431-226)