

HEALTHY MINERAL SUNSCREEN NO SHINE PLUS TINT- zinc oxide cream
Zen Dermatology, Inc.

Active Ingredients:

Zinc Oxide 16%

Purpose:

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.

Warnings:

Keep out of reach of children

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:

Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide, 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.

DRUG FACTS

ACTIVE INGREDIENT: Zinc Oxide 16% **PURPOSE:** Sunscreen

USES:
Helps prevent sunburn. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early 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 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
- **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, Iron Oxide, 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
- May stain some fabrics.

MANUFACTURED FOR:
Zen Dermatology
Sacramento, CA, 95819



skin
ZD
soul

**Healthy Mineral SunScreen
No Shine + Tint**

Broad Spectrum SPF 40
with Ceramides, Zinc Oxide & Antioxidants C & E

net wt. 1.75 oz | 50 g

HEALTHY MINERAL SUNSCREEN NO SHINE PLUS TINT

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85338-208(NDC:58892-208)
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
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CI 77491 (UNII: 1K09F3G675)	
CI 77492 (UNII: EX438O2MRT)	
CERAMIDE 3 (UNII: 4370DF050B)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CI 77499 (UNII: XM0M87F357)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85338-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/17/2024	

Labeler - Zen Dermatology, Inc. (113127065)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85338-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85338-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85338-208)