

NON-TINTED DAILY MINERAL SHIELD- zinc oxide cream
SIGNATURE MED SPA MT LLC

ACTIVE INGREDIENT(S)

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 broken or damaged 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

WARNING

KEEP OUT OF REACH OF CHILDREN

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 a.m. - 2 p.m. 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

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, 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:

Signature Med Spa | Great Falls, Mt 59405
www.yoursignaturemedspa.com
(406) 272 1049



SIGNATURE
m e d s p a

Non-Tinted Daily Mineral Shield

Contains Zinc

No Chemical



Broad Spectrum

Net Wt. 1.75 oz / 50 g

NON-TINTED DAILY MINERAL SHIELD

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85896-226(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
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85896-226-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/02/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/02/2024	

Labeler - SIGNATURE MED SPA MT LLC (082769232)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85896-226)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85896-226)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85896-226)