

# NON-TINTED MINERAL SUNSCREEN- zinc oxide cream

## WECARE FRISCO PLLC

REEF FRIENDLY • NON-COMEDOGENIC • GLUTEN FREE

### 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 sleeve shirts and 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/Hydrogen Dimethicone Silsesquioxane Crosspolymer

### OTHER INFORMATION:

- Protect this product from excessive heat and direct sun

MANUFACTURED FOR:  
WeCareFrisco  
Frisco, TX 75035



WeCare Frisco

WECARE AM-REPLENISH

NON-TINTED MINERAL SUNSCREEN

SPF  
40

BROAD SPECTRUM SPF 40 WITH CERAMIDES,  
ZINC OXIDE & ANTIOXIDANTS C & E

WWW.WECAREFRISCO.COM

net wt. 1.75 oz / 50 g

## NON-TINTED MINERAL SUNSCREEN

zinc oxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85747-226(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
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<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)	
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)	
<b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)	
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)	
<b>CERAMIDE 3</b> (UNII: 4370DF050B)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85747-226-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/16/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/16/2022	

**Labeler** - WECARE FRISCO PLLC (069012846)

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85747-226)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85747-226)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85747-226)