

## **ZINC OXIDE SPF 40 NON-TINTED- zinc oxide cream**

### **Skin Restoration Aesthetics**

-----

#### **Active Ingredient:**

Zinc Oxide 20%

#### **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.

#### **Directions:**

- Apply liberally 15 minutes before sun exposure.
- Reapply: • After 40 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:**

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

#### **Other Information:**

Protect this product from excessive heat and direct sun

## Warning:

Keep out of the reach of children

### DRUG FACTS

#### ACTIVE INGREDIENTS:

Zinc Oxide 20%

#### 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.

#### DIRECTIONS:

- Apply liberally 15 minutes before sun exposure.
- Reapply:
  - After 40 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:

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogren Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

#### OTHER INFORMATION:

- Protect this product from excessive heat and direct sun

#### MANUFACTURED FOR:

The Skin Restoration

San Jose, CA 95131

www.theskinrestoration.com



Zinc Oxide  
SPF 40  
non-tinted

spf 40 broad spectrum  
water resistant (40 minutes)  
sunscreen

Net Wt. 4 oz / 113 g

## ZINC OXIDE SPF 40 NON-TINTED

zinc oxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85296-205
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85296-205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/18/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/18/2024	

**Labeler** - Skin Restoration Aesthetics (134407850)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85296-205)

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85296-205)

Revised: 3/2025

Skin Restoration Aesthetics