

**PROTECT AND RENEW- zinc oxide cream**  
**ENSO SKINCARE & WELLNESS LLC**

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**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 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.

**Warnings:**

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, 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
- May stain some fabrics

### DRUG FACTS

#### 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.

#### 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:

Ensō Skincare and Wellness  
Chandler, AZ 85224  
www.ensoskincarewellness.com  
602-290-0342



## Protect & Renew

### Lightly Tinted Sunscreen

Broad Spectrum SPF 40

Vitamin C + Vitamin E

Non-Comedogenic

Cruelty-Free

Reef Friendly

Net Wt. 1.75 oz / 50 g

## PROTECT AND RENEW

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85971-208(NDC:58892-208)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
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<b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)
<b>CI 77492</b> (UNII: EX438O2MRT)
<b>CI 77499</b> (UNII: XM0M87F357)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)
<b>CERAMIDE 3</b> (UNII: 4370DF050B)
<b>CI 77491</b> (UNII: 1K09F3G675)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85971-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/16/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/16/2022	

**Labeler** - ENSO SKINCARE & WELLNESS LLC (081929914)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85971-208)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85971-208)

### Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85971-208)