

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

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 1.6%

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



3 85971 20850 2



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

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85971-208 |
| 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 |
|-----------------|----------|
|-----------------|----------|

| | |
|--|--|
| CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U) | |
| CYCLOHEXASILOXANE (UNII: XHK3U310BA) | |
| CI 77492 (UNII: EX438O2MRT) | |
| CI 77499 (UNII: XM0M87F357) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR) | |
| CERAMIDE 3 (UNII: 4370DF050B) | |
| CI 77491 (UNII: 1K09F3G675) | |
| CYCLOPENTASILOXANE (UNII: 0THT5PCI0R) | |
| DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |
| DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6) | |
| HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N) | |
| TETRAHEXYLDECYL ASCORBATE (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 |
|------------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing Inc. | | 793406000 | manufacture(85971-208) |

Establishment

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

Revised: 8/2025

ENSO SKINCARE & WELLNESS LLC