

PREMIER ZINC- zinc oxide cream
ENSO SKINCARE & WELLNESS LLC

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 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:

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

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, 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

MANUFACTURED FOR:
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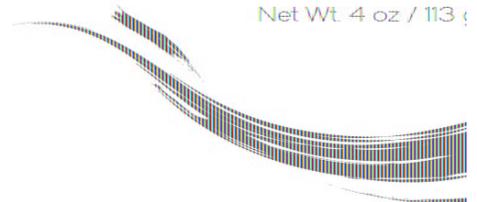


PREMIER
Non-Tinted A
for Body & F
Broad Spectrum
with Vitamin C +

Non-Comedogenic

Reef Friendly

Net Wt. 4 oz / 113 g



PREMIER ZINC

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85971-205(NDC:58892-205)
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
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HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
GLYCERIN (UNII: PDC6A3C0OX)
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
TRIETHANOLAMINE (UNII: 9O3K93S3TK)
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
DIMETHICONE (UNII: 92RU3N3Y1O)
WATER (UNII: 059QF0KO0R)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85971-205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/14/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/14/2023	

Labeler - ENSO SKINCARE & WELLNESS LLC (081929914)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85971-205)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85971-205)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85971-205)

Revised: 12/2025

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