

**COVERED- zinc oxide cream**  
**Potency No. 710 LLC**

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**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.

**Warnings:**

Keep out of reach of children

**Directions:**

- Apply liberally 15 minutes before sun exposure.
- Reapply: • After 80 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.
- May stain some fabrics.

**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 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  
 - Reapply:  
 - After 40 minutes of swimming or sweating  
 - Immediately after towel drying  
 - 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:**  
 C<sub>12-15</sub> 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  
 - May stain some fabrics.

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**COVERED**

zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85319-205
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85319-205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/28/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/28/2019	

**Labeler** - Potency No. 710 LLC (100056294)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85319-205)

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85319-205)

Revised: 3/2025

Potency No. 710 LLC