

**AURA DEFENSE- zinc oxide cream**  
**Grace and Glow MD LLC**

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Zinc Oxide 20%

Sunscreen

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.

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.

Keep out of reach of children

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.

Bismuth Oxychloride, 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, Iron Oxides, Mica, 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

- Protect this product from excessive heat and direct sun
- May stain some fabrics

**DRUG FACTS (continued)**

• **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:**

Bismuth Oxychloride, 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, Iron Oxides, Hydrogren Dimethicone, Mica, 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.

**MANUFACTURED FOR:**

Grace & Glow MD  
Lower Gwynedd, PA, 19002  
www.graceandglowmd.com  
215.618.4868



**AURA DEFENSE  
TINTED SPF 40**

**Mineral Sunscreen  
for Face and Body**

**Zinc Oxide  
Antioxidants C & E**

**Broad Spectrum SPF 40  
Water Resistant (40 minutes)**

Net Wt. 2.1 oz / 60 g

**AURA DEFENSE**

zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:87271-204(NDC:58892-204)
<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	200 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	

<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)
<b>STEARYL DIMETHICONE (400 MPA.S AT 50C)</b> (UNII: R327X197HY)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)
<b>PEG-30 DIPOLYHYDROXYSTEARATE</b> (UNII: 9713Q0S7FO)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>MICA</b> (UNII: V8A1AW0880)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>CI 77491</b> (UNII: 1K09F3G675)
<b>CI 77499</b> (UNII: XM0M87F357)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)
<b>CI 77492</b> (UNII: EX438O2MRT)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87271-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/28/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/28/2025	

**Labeler** - Grace and Glow MD LLC (109490775)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(87271-204)

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(87271-204)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(87271-204)

Revised: 2/2026

Grace and Glow MD LLC