

**RESTORE AND REPLENISH- zinc oxide cream**  
**BELLAGENA SKINCARE STUDIO & SPA**

**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 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
- 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, Tetrahexylidacyl 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:**  
 Bellagena LLC  
 5861 Cortez Rd. W. Brandon FL, 34210  
 941-544-7546 • Bellagena.com

|  |                          |                           |                              |
|--|--------------------------|---------------------------|------------------------------|
| <b>RESTORE AND REPLENISH</b>                                 |                          |                           |                              |
| zinc oxide cream   |                          |                           |                              |
| <b>Product Information</b>                                   |                          |                           |                              |
| <b>Product Type</b>  | HUMAN OTC DRUG           | <b>Item Code (Source)</b> | NDC:85730-208(NDC:58892-208) |
| <b>Route of Administration</b>                               | TOPICAL                  |                           |                              |
| <b>Active Ingredient/Active Moiety</b>                       |                          |                           |                              |
| <b>Ingredient Name</b>                                       | <b>Basis of Strength</b> | <b>Strength</b>           |                              |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE               | 160 mg in 1 g             |                              |
| <b>Inactive Ingredients</b>                                  |                          |                           |                              |
| <b>Ingredient Name</b>                                       | <b>Strength</b>          |                           |                              |

|  |
|--|
| <b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)                                    |
| <b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)                              |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)  |
| <b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)                                   |
| <b>CI 77491</b> (UNII: 1K09F3G675)   |
| <b>CI 77492</b> (UNII: EX438O2MRT)   |
| <b>CI 77499</b> (UNII: XM0M87F357)   |
| <b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                                   |
| <b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)                                  |
| <b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)    |
| <b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)                               |
| <b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)   |
| <b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5) |
| <b>CERAMIDE 3</b> (UNII: 4370DF050B)   |
| <b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)  |
| <b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)                               |
| <b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)                          |

### Packaging

| # | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85730-208-50 | 50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/27/2025           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 05/27/2025           |                    |

**Labeler** - BELLAGENA SKINCARE STUDIO & SPA (114342283)

### Establishment

| Name                 | Address | ID/FEI    | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC |         | 144949372 | analysis(85730-208) |

### Establishment

| Name                        | Address | ID/FEI    | Business Operations    |
|-----------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing INC |         | 793406000 | manufacture(85730-208) |

### Establishment

| Name                        | Address | ID/FEI    | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. |         | 958388357 | relabel(85730-208)  |