

**REPLENISHING DAILY PROTECTION SUNSCREEN INVISIBLE- zinc oxide cream**  
**KATHLEEN P. HUTTON, M.D., INC. A PROFESSIONAL CORPORATION**

**DRUG FACTS (cont)**

- 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:**  
 Kathleen Hutton MD  
 Newport Beach, CA 92660

[WWW.HUTTONKLEIN.COM](http://WWW.HUTTONKLEIN.COM)  
 800-909-0060



**SPF 40**

Replenishing Daily  
 Protection Sunscreen

- Free of Chemical Sunscreens
- Broad Spectrum
- Oil and PABA Free



Net. Wt. 1.75 oz./ 50 g

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**REPLENISHING DAILY PROTECTION SUNSCREEN INVISIBLE**

zinc oxide cream

**Product Information**

|                                |                |                           |                              |
|--------------------------------|----------------|---------------------------|------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:81679-208(NDC:58892-208) |
| <b>Route of Administration</b> | 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 |
|-----------------|----------|
|-----------------|----------|

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

### Packaging

| # | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:81679-208-50 | 50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 04/02/2025           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 04/02/2025           |                    |

**Labeler** - KATHLEEN P. HUTTON, M.D., INC. A PROFESSIONAL CORPORATION (792310955)

### Establishment

| Name                 | Address | ID/FEI    | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC |         | 144949372 | analysis(81679-208) |

### Establishment

| Name                         | Address | ID/FEI    | Business Operations    |
|------------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing Inc. |         | 793406000 | manufacture(81679-208) |

### Establishment

| Name                        | Address | ID/FEI    | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. |         | 958388357 | relabel(81679-208)  |