

AM RESTORE- zinc oxide cream
Minder Day Spa, Inc.

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 10am-2pm
- Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:

Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Cross-polymer, Dimethicone/Vinyl Dimethicone Cross-polymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide (CI 77491), 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 | Savvy Skin Spa
 Solana Beach, CA 92075



savvy skin

SMART SKINCARE SOLUTIONS

AM RESTORE

SPF 40 Broad Spectrum
 Ceramides and Antioxidants C & E

net wt. 1.75 oz | 50 g

DRUG
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AM RESTORE

zinc oxide cream

Product Information

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|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85364-208(NDC:58892-208) |
| Route of Administration | 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 |
|-----------------|----------|
|-----------------|----------|

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85364-208-50 | 50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/13/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 05/13/2020 | |

Labeler - Minder Day Spa, Inc. (042082434)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | analysis(85364-208) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing INC | | 793406000 | manufacture(85364-208) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. | | 958388357 | relabel(85364-208) |