

MORNING REPLENISH- zinc oxide cream
Restore Skin Therapy, LLC

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 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.
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, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Hydrogen Dimethicone Silsesquioxane Crosspolymer
OTHER INFORMATION: Protect this product from excessive heat and direct sun. May stain some fabrics.



restore
skin
therapy

morning
replenish

spf 40 broad spectrum

restore skin therapy LLC
www.restoreksintherapy.com
Barcode: 3 85313 20850 4
Net. Wt. 1.75 oz / 50 g

MORNING REPLENISH
zinc oxide cream

| Product Information | | | |
|-------------------------|----------------|--------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85313-208(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 |

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85313-208-50 | 50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/25/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 05/25/2017 | |

Labeler - Restore Skin Therapy, LLC (071289893)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | analysis(85313-208) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing Inc | | 793406000 | manufacture(85313-208) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. | | 958388357 | relabel(85313-208) |