

NON-TINTED MINERAL FOAMING SUNSCREEN- titanium dioxide, zinc oxide aerosol, foam

Restore Skin Therapy, LLC

DRUG FACTS

ACTIVE INGREDIENTS:

Titanium Dioxide 3%
Zinc Oxide 10%

PURPOSE:

Sunscreen
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:

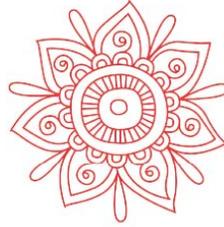
- Shake well before using.
- Push nozzle up to release safety tab.
- Apply liberally 15 minutes before sun exposure.
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
- Children under 6 months: Ask a doctor
- **Sun Protection Measures:** 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:

Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cellulose Gum, Ceteareth 20, Cetearyl Alcohol, Citric Acid, Disodium EDTA, Glycereth-26, Glycerin, Glyceryl Stearate, Methyl Methacrylate Crosspolymer, Microcrystalline Cellulose, Octyldodecyl Neopentanoate, Polymethyl Methacrylate, Polysorbate 80, Polyurethane-2, Trans-1,3,3,3-Tetrafluoropropene, Tricantanyl PVP, Triethoxycaprylylsilane, Trimethoxycaprylylsilane, Water

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun.
- May stain some fabrics.
- Store between 68° to 104° F (20° to 40° C).
- Do not store at temperatures above 120° F.



restore
skin
therapy

non-tinted | mineral
foaming
sunscreen

spf 30 broad spectrum
water resistant (40 mins)

restore skin therapy LLC
www.restoreskintherapy.com



Net. Wt. 3.5 oz / 100 g

NON-TINTED MINERAL FOAMING SUNSCREEN

titanium dioxide, zinc oxide aerosol, foam

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85313-211(NDC:58892-211) |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 100 mg in 1 g |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 30 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3) | |
| GLYCERETH-26 (UNII: NNE56F2N14) | |
| OCTYLDODECYL ERUCATE (UNII: D4N66T98C2) | |
| ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V) | |
| TRIACONTANYL PVP (UNII: N0SS3Q238D) | |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| 1,3,3,3-TETRAFLUOROPROPENE, (1E)- (UNII: 5I2481U008) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| WATER (UNII: 059QF0K00R) | |
| CETEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| GLYCERYL STEARATE (UNII: 230OU9XXE4) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| CELLULOSE GUM (UNII: K679OBS311) | |
| ISODODECANE (UNII: A8289P68Y2) | |
| POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11) | |
| C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ) | |
| CETEARETH-20 (UNII: YRC528SWJY) | |
| CITRIC ACID (UNII: 2968PHW8QP) | |
| ISOHEXADECANE (UNII: 918X1OUF1E) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:85313-211-04 | 113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 08/05/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 08/05/2019 | |

Labeler - Restore Skin Therapy, LLC (071289893)

Registrant - Restore Skin Therapy, LLC (071289893)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|----------------|---------------|----------------------------|
| Custom Analytics LLC | | 144949372 | analysis(85313-211) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|----------------|---------------|----------------------------|
| Fragrance Manufacturing Inc | | 793406000 | manufacture(85313-211) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|----------------|---------------|----------------------------|
| Fallien Cosmeceuticals Ltd. | | 958388357 | relabel(85313-211) |

Revised: 12/2025

Restore Skin Therapy, LLC