

MATTE INVISIBLE MINERAL SUNSCREEN- zinc oxide cream
INTEGRATIVE AESTHETICS BOSTON, LLC

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.

Warnings:

Keep out of reach of children

Directions:

- Apply liberally 15 minutes before sun exposure.
- Reapply: • After 80 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:

Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide, Hydrogen Dimethicone, 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.

DRUG FACTS (cont)

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.



MATTE INVISIBLE MINERAL SUNSCREEN

NON-COMEDOGENIC
CRUELTY-FREE
REEF-FRIENDLY

TINTED
SPF 40 BROAD SPECTRUM

DRUG FACTS

ACTIVE INGREDIENT:

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 sleeve shirts and hats and sunglasses

Distributed by
ClearDermaceuticals, Inc
Watertown, MA
www.cleardermaceuticals.com



NET WT. 1.75 FL OZ / 50 ML

MATTE INVISIBLE MINERAL SUNSCREEN

zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85306-208 |
| 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 |
|-------------------------------|----------|
| CERAMIDE 3 (UNII: 4370DF050B) | |

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

| Packaging | | | | |
|------------------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:85306-208-50 | 50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 12/12/2023 | |

| Marketing Information | | | | |
|------------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC Monograph Drug | M020 | 12/12/2023 | | |

Labeler - INTEGRATIVE AESTHETICS BOSTON, LLC (053676863)

| Establishment | | | |
|------------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Fragrance Manufacturing Inc. | | 793406000 | manufacture(85306-208) |

| Establishment | | | |
|----------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Custom Analytics LLC | | 144949372 | analysis(85306-208) |