

TIZO TINTED MOISTURIZING SERUM - MEDIUM-DEEP- zinc oxide cream
Fallien Cosmeceuticals, Ltd.

Active Ingredients:

Zinc Oxide 15%

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 a.m. - 2 p.m. Wear long-sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients:

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Ceramide 3, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Iron Oxides, Isododecane, Isohexadecane, Lauryl PEG/PPG-18/18 Dimethicone, Magnesium Sulfate, Microcrystalline Wax, Octadecene, PEG-10 Dimethicone, Polyhydroxystearic Acid, Polysorbate 20, Silica, Sodium Chloride, Sodium Hyaluronate, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Titanium Dioxide, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

Other Information:

Protect this product from excessive heat and direct sun. May stain some fabrics. Shake well before using.

Warnings:

Keep out of the reach of children.

DRUG FACTS

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Fallien Cosmeceuticals, Ltd.

Eagleville, PA 19403

Made in USA

TiZO[®]

TINTED MOISTURIZING SERUM

Hyaluronic Acid
Ceramides • Glycerin

Sheer Silky Finish

MEDIUM-DEEP

Broad Spectrum
SPF 30 Sunscreen

Net Wt. 1.75 oz./50 g

TIZO TINTED MOISTURIZING SERUM - MEDIUM-DEEP

zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58892-134 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 150 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CI 77499 (UNII: XM0M87F357) | |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| CERAMIDE 3 (UNII: 4370DF050B) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ) | |
| HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N) | |
| ISOHEXADECANE (UNII: 918X1OUF1E) | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |
| DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX) | |
| MAGNESIUM SULFATE (UNII: DE08037SAB) | |
| SODIUM HYALURONATE (UNII: YSE9PPT4TH) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHANOLAMINE (UNII: 9O3K93S3TK) | |
| WATER (UNII: 059QF0KO0R) | |
| OCTADECENE (UNII: H5ZUQ6V4AK) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| CYCLOPENTASILOXANE (UNII: 0THT5PCI0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| CI 77491 (UNII: 1K09F3G675) | |
| CYCLOHEXASILOXANE (UNII: XHK3U310BA) | |
| ISODODECANE (UNII: A8289P68Y2) | |
| CI 77492 (UNII: EX438O2MRT) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|----------------|---------------------|----------------------|--------------------|
| 1 | NDC:58892-134- | 1 in 1 CARTON | 10/08/2024 | |

| | | | | |
|------------------------------|---|---|-----------------------------|---------------------------|
| 1 | 50 | 1 III 1 CARTON | 10/08/2024 | |
| 1 | | 50 g in 1 TUBE; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M020 | | 10/08/2024 | |

Labeler - Fallien Cosmeceuticals, Ltd. (958388357)

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|----------------------|----------------|---------------|----------------------------|
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Custom Analytics LLC | | 144949372 | analysis(58892-134) |

| | | | |
|------------------------------|----------------|---------------|----------------------------|
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Fragrance Manufacturing Inc. | | 793406000 | manufacture(58892-134) |

Revised: 12/2025

Fallien Cosmeceuticals, Ltd.