

**TIZO TINTED MOISTURIZING SERUM - LIGHT- zinc oxide cream**  
**Fallien Cosmeceuticals, Ltd.**

-----

**Active Ingredient:**

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 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:**

C 12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Ceramide 3, CetylPEG/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 Methicone, 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**

**Active Ingredient:** 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.  
• Reapply at least every 2 hours • Use a water resistant sunscreen if swimming or sweating. • 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:**  
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 Methicone, 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

**Fallien Cosmeceuticals, Ltd.**  
Eagleville, PA 19403  
Made in USA

**TiZO®**

**TINTED  
MOISTURIZING  
SERUM**

Hyaluronic Acid  
Ceramides • Glycerin

Sheer Silky Finish

**LIGHT**

Broad Spectrum  
SPF 30 Sunscreen

Net Wt. 1.75 oz./50 g

## TIZO TINTED MOISTURIZING SERUM - LIGHT

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-131
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	150 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>OCTADECENE</b> (UNII: H5ZUQ6V4AK)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>CERAMIDE 3</b> (UNII: 4370DF050B)	
<b>MAGNESIUM SULFATE</b> (UNII: DE08037SAB)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>STEARYL DIMETHICONE (400 MPA.S AT 50C)</b> (UNII: R327X197HY)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)	
<b>IRON OXIDES</b> (UNII: 1K09F3G675)	
<b>LAURYL PEG/PPG-18/18 METHICONE</b> (UNII: ZJ5S27D9NX)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>SODIUM HYALURONATE</b> (UNII: YSE9PPT4TH)	
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58892-131-50	1 in 1 CARTON	10/08/2024	
-		50 g in 1 TUBE; Type 0: Not a Combination		

Product			
<b>Marketing Information</b>			
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)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(58892-131)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-131)

Revised: 2/2025

Fallien Cosmeceuticals, Ltd.