

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

Active Ingredient:

Zinc Oxide 1%

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 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 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

Active Ingredient: Zinc Oxide 15% **Purpose:** Sunscreen

Uses:
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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

MEDIUM

Broad Spectrum
SPF 30 Sunscreen

Net Wt. 1.75 oz./50 g

TIZO TINTED MOISTURIZING SERUM - MEDIUM

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-133
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
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
IRON OXIDES (UNII: 1K09F3G675)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
ISODODECANE (UNII: A8289P68Y2)	
OCTADECENE (UNII: H5ZUQ6V4AK)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE 3 (UNII: 4370DF050B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
SODIUM HYALURONATE (UNII: YSE9PPT4TH)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-133-50	1 in 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)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(58892-133)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-133)

Revised: 2/2025

Fallien Cosmeceuticals, Ltd.