

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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• 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

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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
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)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
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)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
IRON OXIDES (UNII: 1K09F3G675)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
ISODODECANE (UNII: A8289P68Y2)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
OCTADECENE (UNII: H5ZUQ6V4AK)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-134-50	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(58892-134)

Establishment

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

Revised: 2/2025

Fallien Cosmeceuticals, Ltd.