

TIZO ULTRA ZINC SPF 40 (TINTED)- zinc oxide cream
Fallien Cosmeceuticals, LTD.

Active Ingredients:

Zinc Oxide 20%

Purpose:

Sunscreen

Directions:

Apply liberally 15 minutes before sun exposure.

Warnings:

For external use only. Keep out of the reach of children

Warnings and Directions:

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Bismuth Oxychloride, C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Iron Oxides, Mica, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

Warning:

Keep out of the reach of children.

3 X 6 MM

TiZO[®]

ULTRA ZINC

Tinted



Broad Spectrum SPF 40
Water Resistant (40 Minutes)
Net. Wt. .18 Oz./5 g

DRUG FACTS

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(Purpose):

Zinc Oxide 20%
(Sunscreen)

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Made in USA

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Fallien Cosmeceuticals Ltd.
Eagleville, PA 19403

TIZO ULTRA ZINC SPF 40 (TINTED)

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-319
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
MICA (UNII: V8A1AW0880)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
IRON OXIDES (UNII: 1K09F3G675)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-319-05	5 g in 1 TUBE; Type 0: Not a Combination Product	03/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/15/2022	

Labeler - Fallien Cosmeceuticals, LTD. (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(58892-319)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-319)

Revised: 2/2025

Fallien Cosmeceuticals, LTD.