

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

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**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.

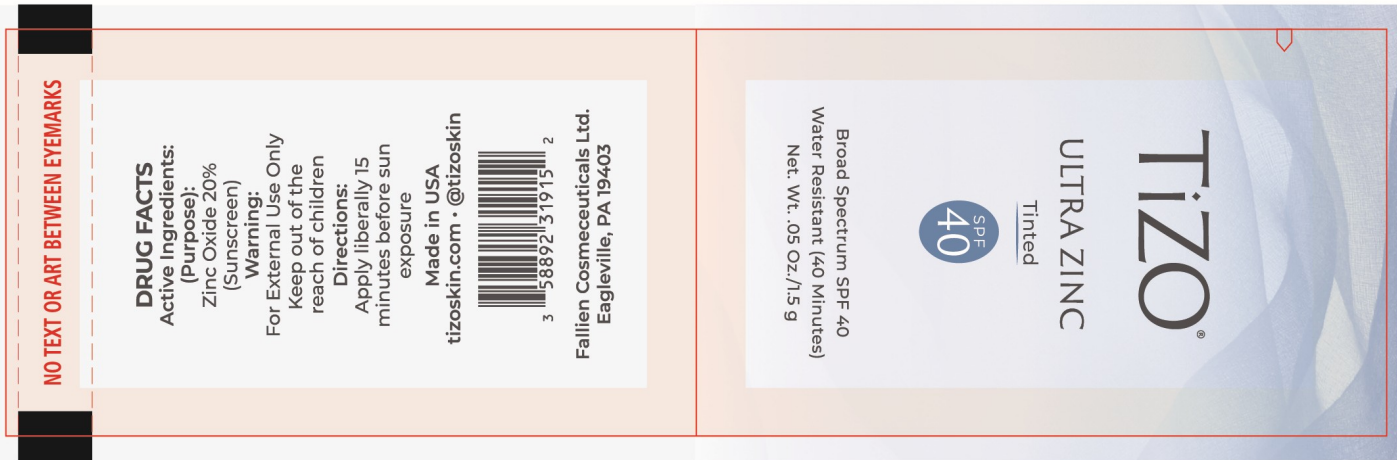
**Warnings and Directions:**

For external use only. Keep out of the reach of children. Apply liberally 15 minutes before sun exposure.

Bismuth Oxochloride, 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.



## TIZO ULTRA ZINC SPF 40 (TINTED)

zinc oxide cream

### Product Information

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

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)	
<b>IRON OXIDES</b> (UNII: 1K09F3G675)	
<b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)	
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>STEARYL DIMETHICONE (400 MPA.S AT 50C)</b> (UNII: R327X197HY)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>PEG-30 DIPOLYHYDROXYSTEARATE</b> (UNII: 9713Q0S7FO)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	

<b>WATER</b> (UNII: 059QF0KO0R)
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-319-15	1.5 g in 1 PACKET; Type 0: Not a Combination Product	03/15/2022	

<b>Marketing Information</b>				
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)

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

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

Revised: 1/2025

Fallien Cosmeceuticals, LTD