

**TIZO3- titanium dioxide, zinc oxide cream**  
**Fallien Cosmeceuticals, LTD**

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Titanium Dioxide 8%

Zinc Oxide 3.8%

Sunscreen

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.

For external use only. Do not use on broken or damaged 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.

Keep out of reach of children

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.

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide (CI 77491), Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

- Protect this product from excessive heat and direct sun
- May stain some fabrics
- PA+++

# TiZO<sup>3</sup>

PRIMER/  
SUNSCREEN

Tinted

SPF  
40

PA+++

FACIAL  
MINERAL SUNSCREEN

*With Antioxidants C & E*

Broad Spectrum SPF 40  
Water Resistant (80 Minutes)  
Net Wt. 3 Oz./85 g

#### DRUG FACTS

**Active Ingredients:** Titanium Dioxide 8%  
Zinc Oxide 3.8%

**Purpose**  
Sunscreen  
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:  
· After 80 minutes of swimming or sweating · Immediately after towel drying · 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 am-2 pm · Wear long-sleeved shirts, pants, hats, and sunglasses

#### Inactive ingredients:

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide (CI 77491), Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

#### Other Information:

· Protect this product from excessive heat and direct sun · May stain some fabrics

#### Fallien Cosmeceuticals, Ltd.

Eagleville, PA 19403  
Made in USA  
www.tizoskin.com

**BACKBAR NOT FOR RESALE**

## TIZO3

titanium dioxide, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-326
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	85.4 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	40.7 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)	
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)	
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)	

<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>CI 77499</b> (UNII: XM0M87F357)
<b>CI 77491</b> (UNII: 1K09F3G675)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>CI 77492</b> (UNII: EX438O2MRT)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>LAURYL PEG/PPG-18/18 METHICONE</b> (UNII: ZJ5S27D9NX)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>ALUMINA</b> (UNII: LMI26O6933)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-326-85	85 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/21/2007	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/21/2007	

**Labeler** - Fallien Cosmeceuticals, LTD (958388357)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(58892-326)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-326)

Revised: 4/2026

Fallien Cosmeceuticals, LTD