

TIZO2- titanium dioxide, zinc oxide cream
Fallien Cosmeceuticals, LTD

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, 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

Principal Display Panel - 50 g Carton Label

TiZO[®]₂

PRIMER/
SUNSCREEN

Non-Tinted

SPF
40

PA++++

**FACIAL
MINERAL SUNSCREEN**

Titanium & Zinc Oxides

Antioxidants C & E

Sheer Matte Finish

Broad Spectrum SPF 40

Water Resistant (80 Minutes)

Net Wt. 1.75 Oz./50 g



Principal Display Panel - 50 g Tube Label

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SUNSCREEN

Non-Tinted

SPF
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PA++++

FACIAL MINERAL SUNSCREEN

With Antioxidants C & E

Broad Spectrum SPF 40

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Fallien Cosmeceuticals, Ltd.

Eagleville, PA 19403

Made in USA

www.tizoskin.com



TIZO2

titanium dioxide, zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58892-336

Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)		Titanium Dioxide	85.4 mg in 1 mL	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)		Zinc Oxide	40.7 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)				
Cyclomethicone 6 (UNII: XHK3U310BA)				
Cyclomethicone 5 (UNII: 0THT5PCI0R)				
Dimethicone 20 (UNII: H8YMB5QY0D)				
Dimethicone Crosspolymer (450000 MPA.S AT 12% in Cyclopentasiloxane) (UNII: UF7620L1W6)				
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4CO0W6C5)				
Dimethiconol (2000 CST) (UNII: T74O12AN6Y)				
Lauryl PEG/PPG-18/18 Methicone (UNII: ZJ5S27D9NX)				
Hydrogen Dimethicone (20 CST) (UNII: 12Z59IF64N)				
PEG-10 Dimethicone (600 CST) (UNII: 8PR7V1SVM0)				
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)				
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-336-50	1 in 1 CARTON	04/27/2015	
1		50 mL 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	02/19/2009	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-336)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-336) , PACK(58892-336)

Revised: 10/2024

Fallien Cosmeceuticals, LTD