

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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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 lime 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

Principal Display Panel - 50 g Carton Label**TiZO[®]₃**

PRIMER/
SUNSCREEN

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

TiZO[®]₃

**PRIMER/
SUNSCREEN**

Tinted

SPF
40

PA+++

FACIAL
MINERAL SUNSCREEN

With Antioxidants C & E

Broad Spectrum SPF 40

Water Resistant (80 Minutes)

Net Wt. 1.75 Oz./50 g

TiZO³

PRIMER/ SUNSCREEN

Tinted



PA+++

FACIAL MINERAL SUNSCREEN

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Fallien Cosmeceuticals, Ltd.

Eagleville, PA 19403

Made in USA

www.tizoskin.com



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TIZO3

titanium dioxide, zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58892-326

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)	
Brown Iron Oxide (UNII: 1N032N7MFO)	
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:58892-326-50	1 in 1 CARTON	03/25/2015	
1		44.4 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 not final	part352	05/21/2007	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-326) , PACK(58892-326)

Revised: 10/2019

Fallien Cosmeceuticals, LTD