

TIZO2- titanium dioxide, zinc oxide cream
Fallien Cosmeceuticals Ltd.

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, Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

PA++++

3 X 6 MM

TiZO₂[®]

PRIMER/ SUNSCREEN

Non-Tinted

SPF
40

PA++++

Broad Spectrum SPF 40
Water Resistant (80 Minutes)
Net. Wt. .18 Oz./5 g

DRUG FACTS

Active Ingredients:

(Purpose):

Titanium Dioxide 8%

(Sunscreen)

Zinc Oxide 3.8%

(Sunscreen)

Warning:

For External Use Only

Directions:

Apply liberally 15
minutes before sun
exposure

Made in USA

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Fallien Cosmeceuticals Ltd.
Eagleville, PA 19403

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
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	40.7 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	85.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ALUMINA (UNII: LMI26O6933)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-336-05	5 mL in 1 TUBE; Type 0: Not a Combination Product	04/27/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/27/2015	

Labeler - Fallien Cosmeceuticals Ltd. (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(58892-336)

Establishment

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

Revised: 4/2026

Fallien Cosmeceuticals Ltd.