

**TIZO PHOTOCEUTICAL AM REPLENISH NON-TINTED- zinc oxide cream**  
**Fallien Cosmeceuticals, LTD**

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**DRUG FACTS**

**Active Ingredients:**

**Zinc Oxide 16%**

**Purpose:**

**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 reach of children. If swallowed, get medical help or contact a poison control center right away.

**Directions:**

- 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

**Inactive Ingredients:**

Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Hydrogen Dimethicone Silsesquioxane Crosspolymer

**Other Information:**

- Protect this product from excessive heat and direct sun.

Keep out of reach of children.

**Principal Display Panel - Carton Label**

**AM  
REPLENISH**

**Non-Tinted  
SPF 40**

**TIZO®**

**PHOTOCEUTICAL®**

***Enhances, protects &  
neutralizes free radicals***

Mineral Sunscreen

Ceramides

Antioxidants C & E

featuring

**SKIN FIRM TECHNOLOGY®**

Broad Spectrum SPF 40

Net Wt. 1.75 oz/50 g



## Principal Display Panel - Tube Label

**TIZO®**

**PHOTOCEUTICAL**

**AM  
REPLENISH**

**Non-Tinted**

Mineral Sunscreen

Ceramides

Antioxidants C & E

featuring

**SKIN FIRM TECHNOLOGY®**

SPF 40

Broad Spectrum

1.75 Fl. Oz/50 mL

# TIZO<sup>®</sup>

## PHOTOCEUTICAL

### AM REPLENISH

Non-Tinted

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Mineral Sunscreen  
Ceramides  
Antioxidants C & E

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*featuring*  
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Fallien Cosmeceuticals Ltd.  
Eagleville, PA 19403  
Made in USA  
www.tizofusion.com



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## TIZO PHOTOCEUTICAL AM REPLENISH NON-TINTED

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-107
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CERAMIDE NP (UNII: 4370DF050B)	
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)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-107-50	1 in 1 CARTON	07/23/2019	
1		50 g 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	03/05/2018	

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

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-107)

**Establishment**

Name	Address	ID/FEI	Business Operations
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Fragrance Manufacturing Inc. (FMI)

793406000

manufacture(58892-107) , pack(58892-107)

Revised: 11/2024

Fallien Cosmeceuticals, LTD