

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

-----  
Zinc Oxide 16%

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.

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

# TIZO<sup>®</sup>

PHOTOCEUTICAL<sup>®</sup>  
SKINCARE

## AM REPLENISH

Lightly Tinted

SPF 40

### MOISTURIZING MINERAL SUNSCREEN

Zinc Oxide  
Ceramides  
Antioxidants C & E

Broad Spectrum SPF 40

Net Wt. 1 oz. / 30 g

### DRUG FACTS

**Active Ingredient:** 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 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.  
• 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 am - 2 pm • 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, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer

#### Other Information:

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

#### Fallien Cosmeceuticals, Ltd.

Eagleville, PA 19403  
Made in USA

@tizoskin



www.tizoskin.com



3 58892 10130 6



## TIZO PHOTOCEUTICAL AM REPLENISH - TINTED

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-101
<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
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CI 77491 (UNII: 1K09F3G675)	
CI 77492 (UNII: EX438O2MRT)	
CERAMIDE 3 (UNII: 4370DF050B)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
CI 77499 (UNII: XM0M87F357)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-101-30	30 g in 1 TUBE; Type 0: Not a Combination Product	10/13/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/13/2015	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(58892-101)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-101)

