

TIZO PHOTOCEUTICAL AM REPLENISH NON-TINTED- 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:

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.

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

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1.75 Fl. Oz/50 mL

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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

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58892-107 |
| Route of Administration | 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 SILSESQUOXANE 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 not final | part352 | 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 |
| Fragrance Manufacturing Inc. (FMI) | | 793406000 | MANUFACTURE(58892-107) , PACK(58892-107) |