

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

Active Ingredient:

Zinc Oxide 16%

(Purpose)

Sunscreen

Directions:

Apply liberally 15 minutes before sun exposure.

Warning:

For external use only.

Warning and Directions:

For external use only. Apply liberally 15 minutes before sun exposure.

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

DRUG FACTS
Active Ingredient:
(Purpose):
Zinc Oxide 16%
(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

TIZO PHOTOCEUTICAL AM REPLENISH - TINTED

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-101
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
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
IRON OXIDES (UNII: 1K09F3G675)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
DIMETHICONE (UNII: 92RU3N3Y10)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-101-15	1.5 g in 1 PACKET; Type 0: Not a Combination Product	07/23/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/23/2019	

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)