

SOLAR PROTECTION FORMULA TIZO SPF 35 SUNSCREEN - zinc oxide lotion
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 20%

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 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.
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - 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 10:00 a.m.-2 p.m.
 - Wear long-sleeved shirts, pants, hats, and sunglasses

Other Information:

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

Inactive Ingredients:

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Methicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexadecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

Manufactured exclusively for
Fallien, Ltd.
West Norriton PA 19403
Made in USA

Principal Display Panel – SPF 35 100g Carton Label

NDC 58892-318-01

SOLAR

PROTECTION

FORMULA[®]

TiZO[®]

For Ultra

Sensitive Skin

20% Zinc Oxide

Pure Mineral Protection

SPF 35

Broad Spectrum

Water Resistant

(40 minutes)

Net Wt. 3.5 Oz./ 100g

NDC 58892-318-01



TIZO
FOR ULTRA SENSITIVE SKIN

20% Zinc Oxide
Pure Mineral Protection

TIZO SPF 35 For Ultra Sensitive Skin

- Specially formulated without irritating chemical sunscreen filters
- Uniquely formulated to offer sheer transparent protection on most complexions
- Silky, smooth aesthetic elegance
- Paraben, oil and fragrance free
- Provides superb photostable performance
- Zinc Oxide helps to assure full spectrum UVA/UVB protection.

Everyone requires daily, year round UVA protection

- UVA radiation is consistently the same all day and all year long
- The effects of UVA damage are cumulative
- UVA radiation is responsible for deep skin damage that results in skin aging, such as wrinkling

DRUG FACTS
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DRUG FACTS

Active Ingredients: Purpose
Zinc Oxide 20%..... Sunscreen

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SPF 35 Broad Spectrum

Water Resistant (40 minutes)

Net Wt. 3.5 Oz./ 100g

- Excellent for Ultra Sensitive Skin
- Dries Translucent
- Full Spectrum Protection



SOLAR PROTECTION FORMULA TIZO SPF 35 SUNSCREEN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-318
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Cetyl PEG/PPG-10/1 Dimethicone (HLB 5) (UNII: 035JKJ76MT)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Dimethicone 100 (UNII: RO266O364U)	
Dimethicone/Diene Dimethicone Crosspolymer (UNII: RSA9I561OK)	
Edetate Disodium (UNII: 7FLD91C86K)	
Methicone (20 cst) (UNII: 6777U11MKT)	
Microcrystalline Wax (UNII: XOF597Q3KY)	
PEG-10 Dimethicone (600 cst) (UNII: 8PR7V1SVM0)	
PEG-30 Dipolyhydroxystearate (UNII: 9713Q0S7FO)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Polyhydroxystearic Acid (2300 MW) (UNII: YXH47AOU0F)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Sodium Chloride (UNII: 451W47IQ8X)	
Stearyl Dimethicone (400 MPA.S AT 50C) (UNII: R327X197HY)	
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Trolamine (UNII: 9O3K93S3TK)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-318-01	1 in 1 CARTON		
1		100 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/02/2012	

Labeler - Fallien Cosmeceuticals, LTD. (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-318)

Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE(58892-318)

Revised: 12/2012

Fallien Cosmeceuticals, LTD.