

SOLAR PROTECTION FORMULA TIZO BODY SUNSCREEN - 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.

Solar Protection Formula TiZO Body Sunscreen

DRUG FACTS

Active Ingredients :

Zinc Oxide 20%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- Provides protection from UVA & UVB rays that may contribute to premature aging of the skin
- Retains SPF up to 40 minutes of water immersion or perspiring

Warnings

- For external use only
- Avoid contact with eyes. In case of eye contact, flush eyes with water thoroughly
- Do not use if sensitive to ingredients
- Discontinue use if irritation occurs. Consult a doctor or healthcare professional if irritation persists
- For use on children less than 6 months of age, consult a doctor
- Keep this and all medicines out of the reach of children
- If swallowed, get medical help or contact a Poison Control Center

Directions

- Apply generously and uniformly to all exposed skin areas before exposure to sunlight
- Continue to rub in until fading occurs, especially in hair bearing areas
- Reapply as needed and after washing, swimming, towel drying, or sweating for maximum protection

Other Information

- Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.
- May stain some fabrics

Inactive Ingredients:

C12-15 Alkyl Benzoate, Caprylhydroxyamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Lauryl PEG/PPG 18/18 Methicone, Methicone, PEG-10 Dimethicone, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexadecyl Ascorbate, Tocopheryl Acetate, Triethanolamine,

Triethoxycaprylsilane, Water

TiZO Body SPF 35 is a sunscreen uniquely formulated to offer sheer, elegant protection with a silky, smooth, matte finish. TiZO Body offers unparalleled aesthetic elegance while providing superb photoprotective performance. Using our proprietary technology, Fallien has formulated multiple particle sizes of micronized zinc oxide into a light, silky texture that dries to a clear, yet matte finish on any complexion. TiZO Body is paraben, oil and fragrance free, and specially formulated without UV absorbing chemicals to offer unsurpassed, irritant free UVA/UVB light protection.

SPF is not Enough

UVA radiation is consistently the same all day and all year long. Everyone requires daily, year round UVA protection. UVA radiation is responsible for deep skin damage that results in most of the changes associated with skin aging, such as wrinkling. In addition, the effects of UVA damage are cumulative. Since the SPF number does not define the level of UVA protection, products that utilize both titanium dioxide and/or zinc oxide, are the best method of assuring full spectrum sun protection from UVA and UVB radiation.

- **Excellent for Sensitive Skin**
- **Free of "Chemical Sunscreen Filters"**
- **Contains no Parabens**
- **Dries Translucent**
- **Full Spectrum Protection**
- **Fragrance Free**

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

Principal Display Panel – Carton Label

NDC 58892-218-01

SOLAR

PROTECTION

Formula[®]

TIZO[®]

BODY

20% Zinc Oxide Mineral Protection

Water Resistant

spf 35

uva/uvb

Net Wt 3.5 oz. / 100g

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TIZO
BODY

20% Zinc Oxide
Mineral Protection

Water Resistant

spf 35
uva/uvb

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zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-218
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
C12-15 Alkyl Benzoate (UNII: A9EJ3J61HQ)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
Cyclomethicone 5 (UNII: 0THT5PC10R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Edetate Disodium (UNII: 7FLD91C86K)	
Glycerin (UNII: PDC6A3C0OX)	
Hydroxystearic Acid (UNII: 933ANU3H2S)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Sodium Chloride (UNII: 451W47IQ8X)	
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
.Alpha.-Tocopherol Acetate, D- (UNII: A7E6112E4N)	
Trolamine (UNII: 9O3K93S3TK)	
Octyltriethoxysilane (UNII: LDC331P08E)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-218-01	1 in 1 CARTON		
1		100 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2010	

Labeler - Fallien Cosmeceuticals, LTD. (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE, PACK

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS

Revised: 9/2010

Fallien Cosmeceuticals, LTD.