

**SOLAR PROTECTION FORMULA SPF 58 SUNSCREEN - titanium dioxide, 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:

Titanium Dioxide 10%

Zinc Oxide 3%

Purpose

Sunscreen

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:

Acrylates C10-30 Alkyl Acrylates Crosspolymer, Butylene Glycol, Butyloctyl Salicylate, Butylparaben, Capric/Caprylic Triglyceride, Cetearyl Alcohol, Cetearyl Glucoside, Cyclomethicone, Dimethicone, Ethylhexyl Hydroxystearate Benzoate, Glyceryl Stearate, Iron Oxides, Isobutylparaben, Isopropylparaben, Melissa Officinalis (Balm Mint) Extract, Octyldodecyl Neopentanoate, PEG-100 Stearate, Phenoxyethanol, Retinyl Palmitate, Simethicone, Sorbitan Laurate, Styrene/Acrylates Copolymer, Talc, Tocopherol, Tocopheryl Acetate, Tricontanyl PVP, Trisodium EDTA, Water, Xanthan Gum

Principal Display Panel – Carton Label

NDC 58892-911-88

**SOLAR
PROTECTION
FORMULA[®]**

Gentle Mineral
Sunscreen

SPF 58
Broad Spectrum
Water Resistant
(40 minutes)

Net Wt. 2.5 Oz./ 70g

UVA and SPF

UVA radiation is consistently the same all day long, all year long. Since the effects of UVA damage are cumulative and UVA rays even penetrate glass, everyone requires daily, year round protection from UVA damage. UVA radiation is responsible for the deeper skin damage that result in most of the destructive changes associated with premature skin aging, (ie, pigmentation changes and wrinkles). Many physicians believe that since the SPF number does not define the level of UVA protection, products with a high SPF number that utilize both titanium dioxide and zinc oxide are the best method of assuring protection from UVA.

NDC 58892-911-88



Gente Mineral Sunscreen

DRUG FACTS Cont.

Inactive Ingredients:
Acrylates C10-30 Alkyl Acrylates
Crosspolymer, Butylene Glycol, Butyloctyl Salicylate, Butylparaben, Capric/Caprylic Triglyceride, Cetearyl Alcohol, Cetearyl Glucoside, Cyclomethicone, Dimethicone, Ethylhexyl Hydroxystearate Benzoate, Glyceryl Stearate, Iron Oxides, Isobutylparaben, Isopropylparaben, Melissa Officinalis (Balm Mint) Extract, Octyldodecyl Neopentanoate, PEG-100 Stearate, Phenoxyethanol, Retinyl Palmitate, Simethicone, Sorbitan Laurate, Styrene/Acrylates Copolymer, Talc, Tocopherol, Tocopheryl Acetate, Tricontanyl PVP, Trisodium EDTA, Water, Xanthan Gum

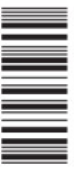
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Extra Gentle No Chemical Sunscreen Filters

Oil, PABA & Fragrance Free Dries Clear

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

Patented

SPF 58
Broad Spectrum
Water Resistant
(40 minutes)

Other Information:
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Net Wt. 2.5 Oz./ 70g

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SOLAR PROTECTION FORMULA SPF 58 SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-911
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	100 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Butylene Glycol (UNII: 3XUS85K0RA)	
Butylparaben (UNII: 3QP11U3FV8)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Cyclomethicone (UNII: NMQ347994Z)	
Dimethicone (UNII: 92RU3N3Y1O)	
Edetate Disodium (UNII: 7FLD91C86K)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
Isobutylparaben (UNII: 0QQJ25X58G)	
Isopropylparaben (UNII: A6EOX47QK0)	
Lemon Balm Oil (UNII: MJ76269K9S)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
Polyoxyl 100 Stearate (UNII: YD01N1999R)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
Sorbitan Monolaurate (UNII: 6W9PS8B71J)	
Talc (UNII: 7SEV7J4R1U)	
Alpha-Tocopherol (UNII: H4N855PNZ1)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Water (UNII: 059QF0K00R)	
Xanthan Gum (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:58892-911-88	1 in 1 CARTON		
1		70 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/02/2004	

Labeler - Fallien Cosmeceuticals, LTD. (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-911)

Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE(58892-911) , PACK(58892-911)

Revised: 12/2012

Fallien Cosmeceuticals, LTD.