

**COTZ SENSITIVE SPF 40 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.*

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**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 a.m. - 2 p.m.
  - Wear long-sleeved shirts, pants, hats, and sunglasses

**Inactive Ingredients:**

C<sub>12-15</sub> Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Getyl 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, Triethanolamine, Triethoxycaprylylsilane, Water

**Other Information:**

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

**Principal Display Panel – SPF 40 100g Carton Label**

**DERMATOLOGIST RECOMMENDED**

**CoTZ®**

**SENSITIVE**

The Healthier Sunscreen™ **Gentle Mineral Complex™ #1 Rated UV Protection\***  
**Will Not Irritate**

Helps Prevent Heat Build-Up in Skin  
which can Damage the Dermis

**100% Free of:**

Chemical Sunscreens, Oils, Fragrances

SPF 40

Broad

Spectrum

UVA-UVB

Soft & Sheer

Water Resistant

(40 minutes)

Net Wt. 3.5 oz/100 g

CōTZ<sup>®</sup>  
SENSITIVE  
The Healthier Sunscreen™

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CōTZ<sup>®</sup> SENSITIVE with Gentle Mineral Complex™ helps prevent heat build-up in the skin, which can damage the dermis. CōTZ<sup>®</sup> helps prevent pre-mature skin aging (fine lines, wrinkles, sagging, age spots), uneven skin tone and other serious problems.

CōTZ<sup>®</sup> sits invisibly on top of the skin and functions like thousands of mirrors to deflect UVA-UVB rays before the rays can touch the skin.

CōTZ<sup>®</sup> is 100% Free of chemical sunscreen ingredients, here's why:

- Chemical sunscreens absorb UVA-UVB rays into the skin and transform the rays into heat, which can damage the dermis. Chemical sunscreens are known to irritate skin.

CōTZ<sup>®</sup>  
SENSITIVE

The Healthier Sunscreen™

CōTZ<sup>®</sup> SENSITIVE with Gentle Mineral Complex™ keeps harmful UV rays from touching the skin, while soothing sensitive or easily irritated skin.

Gentle enough for special skin types and conditions:

- Laser, Cosmetic Surgery, Microdermabrasion, Acid Peel
- Acne, Rosacea
- Psoriasis, Eczema, Lupus/ Rheumatology
- Sun-Sensitive due to medical procedures & medications

CōTZ<sup>®</sup> with Gentle Mineral Complex™ for healthier skin:

- 100% Free of Chemical Sunscreens, Fragrances, Oils, Preservatives, PABA, Gluten, Phthalates
- Will not irritate or sting
- SPF 40 exceeds the level recommended by Skin Cancer experts
- Provides broad spectrum UVA-UVB protection
- Photostable, will not breakdown when exposed to sunlight
- Water Resistant (40 Minutes)
- Non-Greasy

\*Contains #1 rated sun protection ingredient for UVA-UVB rays

Not tested on animals

Manufactured exclusively for CōTZ<sup>®</sup> Skincare  
West Norriton, PA 19403  
www.cotzskincare.com

Gentle Mineral Complex™  
#1 Rated UV Protection\*  
Will Not Irritate

Helps Prevent Heat Build-Up in Skin  
which can Damage the Dermis

100% Free of:  
Chemical Sunscreens, Oils, Fragrances

Soft & Sheer  
Water Resistant  
(40 minutes)

SPF 40  
Broad  
Spectrum  
UVA-UVB

Net Wt. 3.5 oz/100 g

Made in U.S.A.



**COTZ SENSITIVE SPF 40 SUNSCREEN**

zinc oxide lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-418
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: 0THT5PC10R)	
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: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-418-01	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	03/30/2012	

**Labeler** - Fallien Cosmeceuticals, LTD. (958388357)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Custom Analytics LLC		144949372	ANALYSIS(58892-418)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Process Technologies & Packaging		809172885	MANUFACTURE(58892-418)

Revised: 12/2012

Fallien Cosmeceuticals, LTD.