

**COTZ FACE (FOR LIGHTER SKIN TONES) SPF 40 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.*

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**DRUG FACTS**

**Active Ingredients :**

Titanium Dioxide 8%

Zinc Oxide 3.8%

**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 80 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:**

Alumina, Cyclohexasiloxane, Cydopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG 18/18 Methicone, Methicone, PEG-10 Dimethicone

**Other Information:**

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

**Principal Display Panel – 1.5 oz Carton Label****DERMATOLOGIST RECOMMENDED****CoTZ®****FACE****The Healthier Sunscreen™****Silky Soft****Sheer Matte Finish**

Balanced Mineral Complex™ Helps Prevent  
Heat Build-Up in Skin, which can  
Damage the Dermis

100% Free of:

Preservatives, Chemical Sunscreens, Oils

***SPF 40******Broad******Spectrum*****UVA-UVB**For Lighter  
Skin TonesWater Resistant  
(80 minutes)

Net Wt. 1.5 oz/42.5 g

# CōTZ<sup>®</sup> FACE

The Healthier Sunscreen™

DERMATOLOGIST RECOMMENDED

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

CōTZ<sup>®</sup> sits invisibly on top of 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.

# CōTZ<sup>®</sup> FACE

The Healthier Sunscreen™

## Silky Soft Sheer Matte Finish

Balanced Mineral Complex™ Helps Prevent Heat Build-Up in Skin, which can Damage the Dermis

**100% Free of:**  
Preservatives, Chemical Sunscreens, Oils

For Lighter  
Skin Tones  
Water Resistant  
(80 minutes)

**SPF 40  
Broad  
Spectrum  
UVA-UVB**

Net Wt. 1.5 oz/42.5 g

Made in U.S.A.

CōTZ<sup>®</sup> for Face with Balanced Mineral Complex™ for a sheer matte finish

- Leaves skin silky, soft & smooth
- Non-Shiny, Non-Greasy
- Layers invisible under makeup
- Weightless

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

- 100% Free of Oils, Chemical Sunscreens, Preservatives, Fragrances, PABA, Gluten, Phthalates
- Will not irritate or sting
- Gentle enough for all skin types
- Contains #1 and #2 rated sun protection ingredient for UVA-UVB rays
- SPF 40 exceeds the level recommended by Skin Cancer experts
- Provides broad spectrum UVA-UVB protection
- Photostable, will not breakdown when exposed to sunlight

Not tested on animals

Manufactured exclusively for CōTZ<sup>®</sup> Skincare West Norriton, PA 19403  
[www.cotzskincare.com](http://www.cotzskincare.com)



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# COTZ FACE (FOR LIGHTER SKIN TONES) SPF 40 SUNSCREEN

titanium dioxide, zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-347
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	80 mg in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	38 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Aluminum Oxide</b> (UNII: LMI26O6933)	
<b>Cyclomethicone 6</b> (UNII: XHK3U310BA)	
<b>Cyclomethicone 5</b> (UNII: 0THT5PC10R)	
<b>Dimethicone 20</b> (UNII: H8YMB5QY0D)	
<b>Dimethicone/Diene Dimethicone Crosspolymer</b> (UNII: RSA9I561OK)	
<b>Dimethiconol (100000 cst)</b> (UNII: OSA9UP217S)	
<b>Lauryl PEG/PPG-18/18 Methicone</b> (UNII: ZJ5S27D9NX)	
<b>Methicone (20 cst)</b> (UNII: 6777U11MKT)	
<b>PEG-10 Dimethicone (600 cst)</b> (UNII: 8PR7V1SVM0)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-347-45	1 in 1 CARTON		
1		42.5 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/19/2012	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-347)

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## Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE(58892-347)

Revised: 1/2013

Fallien Cosmeceuticals, LTD.