

# **COTZ FACE PRIME AND PROTECT SPF 40 (NON-TINTED)- 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 two 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, Cyclopentasiloxane, Dimethicone. Dimethicone Crosspolymer. Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG-18/18-Hydrogen Dimethicone, Hydrogen Dimethicone, PEG-10 Dimethicone

**Other Information:**

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

**Manufactured Exclusively For:**

CoTZ® Skincare  
Norristown. PA 19403

[www.cotzskincare.com](http://www.cotzskincare.com)

**Principal Display Panel - 42.5 g Carton Label**

**CoTZ®**

the HEALTHIER  
SUNSCREEN®

**Face  
Prime & Protect**

Non-Tinted

SPF  
**40**

**Sheer Matte**

MINERAL SUNSCREEN

**PA +++++**

FACIAL PRIMER

Broad Spectrum SPF 40  
Water Resistant (80 minutes)

Net Wt. 1.5 oz/42.5 g

**CōTZ**  
 THE HEALTHIER  
 SUNSCREEN®

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 CōTZ® Skincare  
 Norristown, PA 19403

www.cotzskincare.com

CōTZ® The Healthier Sunscreen works by reflecting harmful UVA-UVB rays before they can penetrate the skin.



MINERAL SUNSCREEN

100% FREE OF:

Chemical Sunscreens,  
 Oils, Preservatives,  
 Fragrances, Parabens,  
 Gluten, Phthalates

CōTZ® Face Prime & Protect SPF 40 is a sheer, mineral sunscreen providing broad spectrum UVA-UVB protection in a silky, translucent primer. Layers beautifully under makeup, or can be used alone for a smooth matte finish. Non-tinted formula is ideal for lighter skin tones.

- Non-tinted
- Weightless matte finish
- Helps prevent signs of aging

Also available in tinted formula



Face  
**Prime & Protect**

Non-Tinted

SPF  
**40**

Sheer Matte  
 MINERAL SUNSCREEN  
 PA ++++

**FACIAL PRIMER**

Broad Spectrum SPF 40  
 Water Resistant (80 minutes)  
 Net Wt. 1.5 oz/42.5 g



REEF FRIENDLY



WATER RESISTANT



NO ANIMAL TESTING



PRESERVATIVE FREE



TSA APPROVED



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# COTZ FACE PRIME AND PROTECT SPF 40 (NON-TINTED)

titanium dioxide, zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-348
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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

<b>Ingredient Name</b>	<b>Strength</b>
<b>Aluminum Hydroxide</b> (UNII: 5QB0T2IUN0)	
<b>Cyclomethicone 6</b> (UNII: XHK3U310BA)	
<b>Cyclomethicone 5</b> (UNII: 0THT5PCI0R)	
<b>Dimethicone 20</b> (UNII: H8YMB5QY0D)	
<b>Dimethicone Crosspolymer (450000 MPA.S AT 12% in Cyclopentasiloxane)</b> (UNII: UF7620L1W6)	
<b>Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle)</b> (UNII: 9E4C00W6C5)	
<b>Dimethiconol (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>Lauryl PEG/PPG-18/18 Methicone</b> (UNII: ZJ5S27D9NX)	
<b>Hydrogen Dimethicone (20 CST)</b> (UNII: 12Z59IF64N)	
<b>PEG-10 Dimethicone (600 CST)</b> (UNII: 8PR7V1SVM0)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58892-348-45	1 in 1 CARTON	11/15/2018	
1		42.5 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	11/15/2018	

**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(58892-348)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-348) , PACK(58892-348)

Revised: 6/2021

Fallien Cosmeceuticals, LTD