

COTZ FACE PRIME AND PROTECT SPF 40 (TINTED)- titanium dioxide, zinc oxide cream

Fallien Cosmeceuticals, LTD

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

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

Principal Display Panel - 42.5 g Carton Label

CoTZ®

the HEALTHIER

SUNSCREEN®

Face

Prime & Protect

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



Face Prime & Protect

Tinted

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

COTZ FACE PRIME AND PROTECT SPF 40 (TINTED)

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-354
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
Aluminum Oxide (UNII: LMI26O6933)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Dimethicone 20 (UNII: H8YMB5QY0D)	
Dimethicone Crosspolymer (450000 MPA.S AT 12% in Cyclopentasiloxane) (UNII: UF7620L1W6)	
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4CO0W6C5)	
Dimethiconol (2000 CST) (UNII: T74O12AN6Y)	
Brown Iron Oxide (UNII: 1N032N7MFO)	
Lauryl PEG/PPG-18/18 Methicone (UNII: ZJ5S27D9NX)	
Hydrogen Dimethicone (20 CST) (UNII: 12Z59IF64N)	
PEG-10 Dimethicone (600 CST) (UNII: 8PR7V1SVM0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-354-45	1 in 1 CARTON	05/01/2021	
1		42.5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/26/2012	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-354)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-354) , PACK(58892-354)

Revised: 1/2025

Fallien Cosmeceuticals, LTD