

COTZ FACE MOISTURE- zinc oxide cream
Fallien Cosmeceuticals Ltd.

Zinc Oxide 16%

Sunscreen

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.

For external use only. Do not use on broken or damaged 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 reach of children. If swallowed, get medical help or contact a poison control center right away.

Keep out of reach of children

Apply liberally 15 minutes before sun exposure. Use a water-resistant product if swimming or sweating. Reapply 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.

Caprylic/Capric Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer



Face Moisture

Lightly Tinted

SPF
35

MINERAL SUNSCREEN

FACE

Broad Spectrum SPF 35
Water Resistant (80 minutes)
Net Wt. 0.18 oz/5 g

DRUG FACTS

Active Ingredients:

(Purpose)

Zinc Oxide 16%

(Sunscreen)

Warning:

For external use only

Directions:

· Apply liberally 15
minutes before sun
exposure

Keep out of the
reach of children

@cotzskincare



CōTZ Skincare
Norristown, PA 19403
www.cotzskincare.com

COTZ FACE MOISTURE

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-360
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CI 77492 (UNII: EX438O2MRT)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	

CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
DIMETHICONE (UNII: 92RU3N3Y1O)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
CERAMIDE 3 (UNII: 4370DF050B)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
CI 77499 (UNII: XM0M87F357)
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)
CI 77491 (UNII: 1K09F3G675)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-360-18	5 g in 1 TUBE; Type 0: Not a Combination Product	02/04/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/04/2019	

Labeler - Fallien Cosmeceuticals Ltd. (958388357)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(58892-360)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-360)