COTZ FACE MOISTURE- 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.

Drug Facts

Active Ingredients:

Zinc Oxide 16%

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 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:

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

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 – Carton Label

CoTZ®

the HEALTHIER SUNSCREEN®

Face

Moisture

Lightly Tinted

SPF

35

Hydrate & Protect

MINERAL SUNCREEN

FACE

Broad Spectrum SPF 35

Water Resistant (80 Minutes)

Net Wt. 1.5 oz/42.5 g



Principal Display Panel – Tube Label

CoTZ®

the HEALTHIER SUNSCREEN®

Face

Moisture

Lightly Tinted

SPF

35

Hydrate & ProtectMINERAL SUNCREEN

FACE

Broad Spectrum SPF 35 Water Resistant (80 Minutes) Net Wt. 1.5 oz/42.5 g



Face Moisture

Lightly Tinted

35

Hydrate & Protect
MINERAL SUNSCREEN



Active Ingredients: 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:

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Directions:

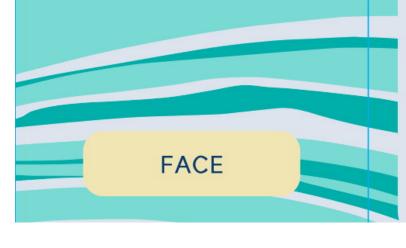
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Manufactured Exclusively For:

CōTZ® Skincare Norristown, PA 19403



Broad Spectrum SPF 35 Water Resistant (80 minutes) Net Wt. 1.5 oz/42.5 g

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	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
CERAMIDE NP (UNII: 4370 DF0 50 B)		
Cyclomethicone 6 (UNII: XHK3U310BA)		
Cyclomethicone 5 (UNII: 0THT5PCI0R)		
Dimethicone 20 (UNII: H8 YMB5QY0D)		
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)		
Hydrogen Dimethicone (20 CST) (UNII: 12Z59IF64N)		
PEG-10 Dimethicone (600 CST) (UNII: 8 PR7V1SVM0)		
POLYHYDRO XYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)		
VINYL DIMETHICO NE/METHICO NE SILSESQUIO XANE CROSSPO LYMER (UNII: 9 NH1UDD2RR)		

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-360-42	1 in 1 CARTON	02/04/2019	
1		42.5 g in 1 TUBE; Type 0: Not a Combination Product		

	Marketing Inform	nation		
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part352	02/04/2019	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-360), PACK(58892-360)

Revised: 1/2021 Fallien Cosmeceuticals, LTD