

COTZ PLUS SPF 58 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.

DRUG FACTS

Active Ingredients:

Titanium Dioxide 10%

Zinc Oxide 3%

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 40 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:

Acrylates C₁₀₋₃₀ Alkyl Acrylates Crosspolymer, Butylene Glycol, Butyloctyl Salicylate, Butylparaben, Capric/Caprylic Triglyceride, Cetearyl Alcohol, Cetearyl Glucoside, Cyclomethicone, Dimethicone, Ethylhexyl Hydroxystearate Benzoate, Glyceryl Stearate, Iron Oxides, Isobutylparaben, Isopropylparaben, Melissa Officinalis (Balm Mint) Leaf Extract, Octyldodecyl Neopentanoate, PEG-100 Stearate, Phenoxyethanol, Retinyl Palmitate, Simethicone, Sorbitan Laurate, Styrene/Acrylates Copolymer, Talc, Tocopherol, Tocopheryl Acetate, Tricontanyl PVP, Trisodium EDTA, Water, Xanthan Gum

Other Information:

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

Principal Display Panel – 2.5 oz Carton Label**DERMATOLOGIST RECOMMENDED****CoTZ®****PLUS****The Healthier Sunscreen™****Balanced Mineral Complex™****#1 Rated UV Protection*****Will Not Irritate or Sting**

Helps Prevent Heat Build-Up in Skin
which can Damage the Dermis

100% Free of:

Chemical Sunscreens & Oils

SPF 58 Broad***Spectrum*****UVA-UVB**

Blends

Translucent

Water

Resistant

(40 minutes)

Net Wt. 2.5 oz/70.0 g

CōTZ[®] PLUS

The Healthier Sunscreen™

DERMATOLOGIST RECOMMENDED

CōTZ[®] PLUS SPF 58 with Balanced Mineral Complex™ helps prevent heat build-up in the skin, which can damage the dermis. CōTZ[®] helps prevent pre-mature skin aging (fine lines, wrinkles, sagging, age spots), uneven skin tone and other serious problems.

CōTZ[®] sits invisibly on top of the skin and functions like thousands of mirrors to deflect UVA-UVB rays before the rays can touch the skin.

CōTZ[®] PLUS

The Healthier Sunscreen™

CōTZ[®] PLUS SPF 58 for maximum protection & healthier skin:

- 100% Free of Chemical Sunscreens, Oils, Fragrances, PABA, Gluten, Phthalates
- Will not irritate or sting
- Gentle for all skin types
- SPF 58 exceeds the level recommended by Skin Cancer experts
- Provides broad spectrum UVA-UVB protection

Balanced Mineral Complex™
#1 Rated UV Protection*
Will Not Irritate or Sting

Helps Prevent Heat Build-Up in Skin
which can Damage the Dermis

100% Free of:
Chemical Sunscreens & Oils

Blends
Translucent
Water
Resistant
(40 minutes)

SPF 58
Broad
Spectrum
UVA-UVB

Net Wt. 2.5 oz/70.0 g

- Photostable, will not breakdown when exposed to sunlight
- Water Resistant (40 Minutes)
- Blends translucent
- Non-greasy

*Contains #1 and #2 rated sun protection ingredients for UVA-UVB rays

Not tested on animals

Manufactured
exclusively for
CōTZ[®] Skincare
West Norriton,
PA 19403
www.cotzskincare.com

CōTZ[®] 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.

Made in U.S.A.

DRUG FACTS

Active Ingredients:	Purpose
Titanium Dioxide 10%	Sunscreen
Zinc Oxide 3%	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 40 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:

Acrylates C₁₂₋₃₀ Alkyl Acrylates Crosspolymer, Butylene Glycol, Butyloctyl Salicylate, Butylparaben, Capric/Caprylic Triglyceride, Cetearyl Alcohol, Cetearyl Glucoside, Cyclomethicone, Dimethicone, Ethylhexyl Hydroxystearate Benzoate, Glyceryl Stearate, Iron Oxides, Isobutylparaben, Isopropylparaben, Melissa Officinalis (Balm Mint) Leaf Extract, Octyldodecyl Neopentanoate, PEG-100 Stearate, Phenoxyethanol, Retinyl Palmitate, Sirmethicone, Sorbitan Laurate, Styrene/Acrylates Copolymer, Talc, Tocopherol, Tocopheryl Acetate, Tricontanyl PVP, Trisodium EDTA, Water, Xanthan Gum

Other Information:

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



COTZ PLUS SPF 58 SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	100 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Butylene Glycol (UNII: 3XUS85K0RA)	
Butylparaben (UNII: 3QPI1U3FV8)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked) (UNII: 809Y72KV36)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Cyclomethicone (UNII: NMQ347994Z)	
Dimethicone (UNII: 92RU3N3Y1O)	
Edetate Trisodium (UNII: 420IP921MB)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Isobutylparaben (UNII: 0QQJ25X58G)	
Isopropylparaben (UNII: A6EOX47QK0)	
Melissa Officinalis Leaf (UNII: 50D2ZE9219)	
Octyldodecyl Neopentanoate (UNII: X8725R883T)	
PEG-100 Stearate (UNII: YD01N1999R)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
Sorbitan Monolaurate (UNII: 6W9PS8B71J)	
Talc (UNII: 7SEV7J4R1U)	
Tocopherol (UNII: R0ZB2556P8)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Tricontanyl Povidone (4 Tricontanyl Branches/Repeat) (UNII: N0SS3Q238D)	
Water (UNII: 059QF0K00R)	
Xanthan Gum (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-070-58	1 in 1 CARTON		
1		70 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/03/2012	

Labeler - Fallien Cosmeceuticals, LTD. (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-070)

Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE(58892-070) , PACK(58892-070)

Revised: 1/2013

Fallien Cosmeceuticals, LTD.