

COTZ PEDIATRIC SPF 40 SUNSCREEN - zinc oxide lotion
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 20 %

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 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:

C₁₂₋₁₅ Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Getyl PEG/PPG 10/1 Dimethicone,

Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Methicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexadecyl Ascorbate, Triethanolamine, Triethoxycaprylylsilane, Water

Other Information:

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

Principal Display Panel – SPF 40 100g Carton Label

PEDIATRICIAN RECOMMENDED

CoTZ®

PEDIATRIC

The Healthier Sunscreen™ **Gentle 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 & Fragrances

SPF 40

Broad

Spectrum

UVA-UVB

Easy to Apply

Water Resistant

(40 minutes)

Net Wt. 3.5 oz/100 g

CōTZ[®]
PEDIATRIC
 The Healthier Sunscreen™

PEDIATRICIAN RECOMMENDED

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CōTZ[®] PEDIATRIC with Gentle Mineral Complex™ is Pediatrician Recommended and helps prevent heat build-up in children's skin, which can damage the dermis. CōTZ[®] helps prevent burning & skin damage, which can lead to uneven skin tone and other serious skin problems.

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

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.

CōTZ[®]
PEDIATRIC

The Healthier Sunscreen™

CōTZ[®] PEDIATRIC with Gentle Mineral Complex™ protects your child's skin:

- Extra gentle for a child's thinner skin
- Suitable for Infants, Toddlers, School-Age Children (age: 6+ months)
- Will not irritate or sting
- SPF 40 exceeds the level recommended by Skin Cancer experts
- Provides broad spectrum UVA-UVB protection
- Photosable, will not breakdown when exposed to sunlight
- Water Resistant (40 Minutes)

CōTZ[®] with Gentle Mineral Complex™ for healthier skin:

- 100% Free of Chemical Sunscreens, Fragrances, Oils, Preservatives, PABA, Gluten, Phthalates
- Goes on soft & sheer
- Blends translucent to form a protective barrier
- Non-greasy

*Contains #1 rated sun protection ingredient for UVA-UVB rays

Gentle 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 & Fragrances

Easy to Apply
 Water Resistant
 (40 minutes)



Net Wt. 3.5 oz/100 g

Not tested on animals

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

Made in U.S.A.



COTZ PEDIATRIC SPF 40 SUNSCREEN
 zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-518
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Cetyl PEG/PPG-10/1 Dimethicone (HLB 5) (UNII: 035JKJ76MT)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
Cyclomethicone 5 (UNII: 0THT5PC10R)	
Dimethicone 100 (UNII: RO266O364U)	
Dimethicone/Diene Dimethicone Crosspolymer (UNII: RSA9I561OK)	
Edetate Disodium (UNII: 7FLD91C86K)	
Methicone (20 cst) (UNII: 6777U11MKT)	
Microcrystalline Wax (UNII: XOF597Q3KY)	
PEG-10 Dimethicone (600 cst) (UNII: 8PR7V1SVM0)	
PEG-30 Dipolyhydroxystearate (UNII: 9713Q0S7FO)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Polyhydroxystearic Acid (2300 MW) (UNII: YXH47AOU0F)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Sodium Chloride (UNII: 451W47IQ8X)	
Stearyl Dimethicone (400 MPA.S AT 50C) (UNII: R327X197HY)	
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Trolamine (UNII: 9O3K93S3TK)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-518-01	1 in 1 CARTON		
1		100 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part352	09/07/2012	

Labeler - Fallien Cosmeceuticals, LTD. (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-518)

Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging		809172885	MANUFACTURE(58892-518)

Revised: 12/2012

Fallien Cosmeceuticals, LTD.