

**COTZ SENSITIVE- 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 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 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:**

C<sub>12-15</sub> Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl

Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexydecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

**Other Information:**

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

**Manufactured Exclusively For:**

CoTZ<sup>®</sup> Skincare  
Norristown, PA 19403

[www.cotzskincare.com](http://www.cotzskincare.com)

**Principal Display Panel – CoTZ Sensitive Tube Label**

**CoTZ<sup>®</sup>**

the HEALTHIER  
SUNSCREEN<sup>®</sup>

**Sensitive**

Non-Tinted

SPF

**40**

**Gentle Zinc Oxide**

MINERAL SUNSCREEN

FACE & BODY

Broad Spectrum SPF 40

Water Resistant (40 minutes)

Net Wt. 3.5 oz/100 g



## Principal Display Panel – CoTZ Sensitive Carton Label

**CoTZ®**

the HEALTHIER  
SUNSCREEN®

**Sensitive**

Non-Tinted

SPF

**40**

**Gentle Zinc Oxide**

MINERAL SUNSCREEN

FACE & BODY

Broad Spectrum SPF 40

Water Resistant (40 minutes)

Net Wt. 3.5 oz/100 g

**CōTZ**<sup>®</sup>  
the HEALTHIER  
SUNSCREEN<sup>®</sup>

**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 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:**  
C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG PPG 10-1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexydecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

**Other Information:**  
- Protect this product from excessive heat and direct sun.  
- May stain some fabrics.

Manufactured Exclusively For:  
CōTZ<sup>®</sup> Skincare  
Norristown, PA 19403

www.cotzskincare.com

CōTZ<sup>®</sup> The Healthier Sunscreen works by reflecting harmful UVA-UVB rays before they can penetrate the skin.



**MINERAL SUNSCREEN**

**100% FREE OF:**

Chemical Sunscreens,  
Oils, Preservatives, Fragrances,  
Parabens, Gluten, Phthalates

CōTZ<sup>®</sup> Sensitive SPF 40 Mineral Sunscreen protects and soothes sensitive or easily irritated skin. Gentle, non-tinted cream blends translucent, leaving a soft, sheer finish. 20% Zinc Oxide is Dermatologist Recommended for even the most sensitive skin.

- Non-tinted
- Moisturizing
- Non-irritating
- Helps prevent signs of aging



**Sensitive**

Non-Tinted

SPF  
**40**

**Gentle Zinc Oxide  
MINERAL SUNSCREEN**

**FACE & BODY**

Broad Spectrum SPF 40  
Water Resistant (40 minutes)  
Net Wt. 3.5 oz/100 g



REEF FRIENDLY



WATER RESISTANT



NO ANIMAL TESTING



PRESERVATIVE FREE



3 58892 41801 5

# COTZ SENSITIVE

zinc oxide cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-410
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: 0THF5PCI0R)	
DIMETHICONE 100 (UNII: RO266O364U)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STEARYL DIMETHICONE (400 MPAS AT 50C) (UNII: R327X197HY)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-410-01	1 in 1 CARTON	11/26/2018	
1		100 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 not final	part352	02/15/2015	

**Labeler** - Fallien Cosmeceuticals, LTD (958388357)

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-410)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-410) , PACK(58892-410)

Revised: 1/2021

Fallien Cosmeceuticals, LTD