

COTZ KIDS- zinc oxide cream
Fallien Cosmeceuticals, LTD.

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 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.

Warnings:

Keep out of reach of children

Directions:

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.

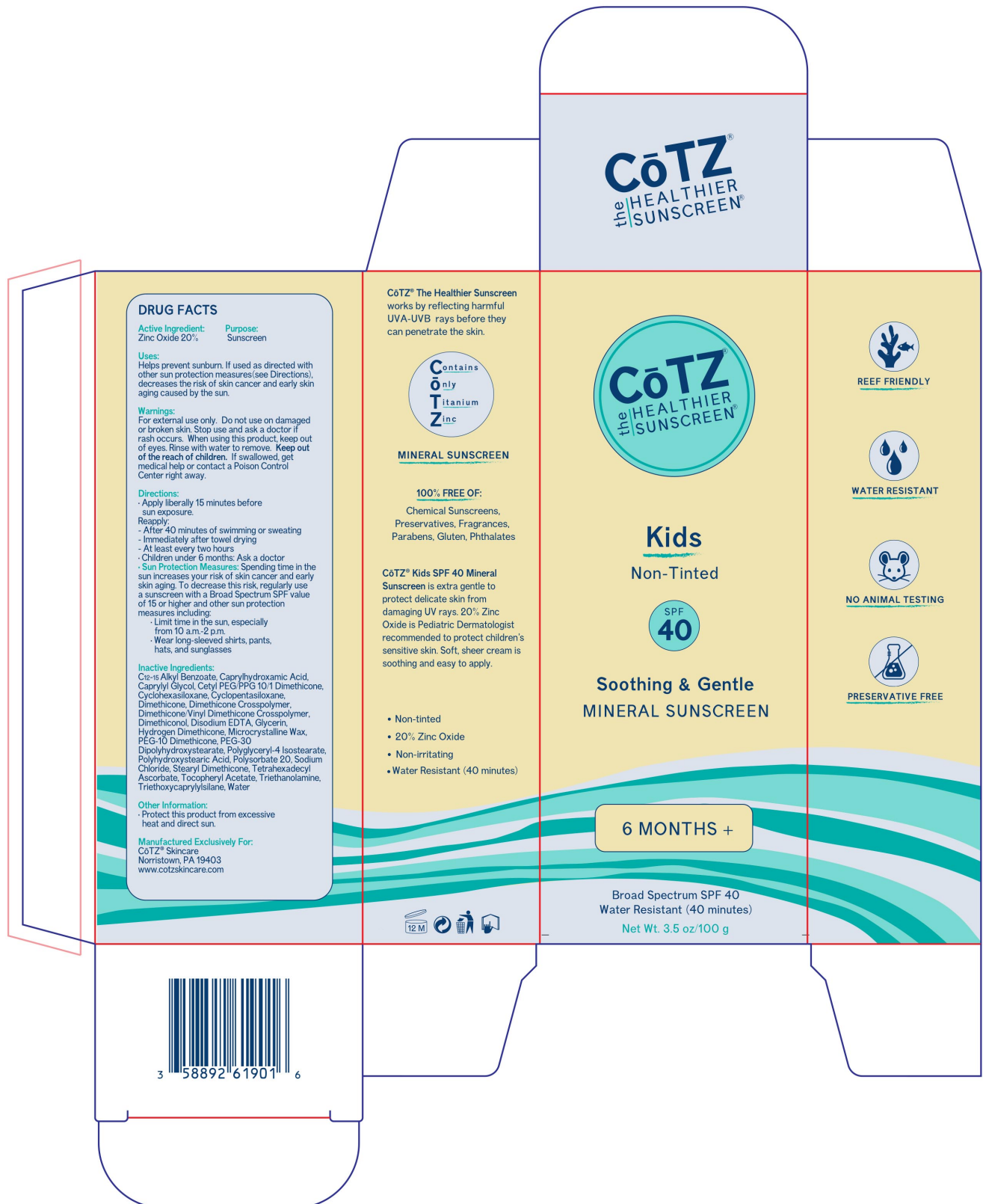
Inactive Ingredients:

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, Tetrahexyldecyl Ascorbate,

Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

Other Information:

- Protect this product from excessive heat and direct sun



COTZ KIDS

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-619
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
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
WATER (UNII: 059QF0KO0R)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-619-01	1 in 1 CARTON	08/18/2025	

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 Drug	M020		08/18/2025	

Labeler - Fallien Cosmeceuticals, LTD. (958388357)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(58892-619)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-619)

Revised: 8/2025

Fallien Cosmeceuticals, LTD.