

TIZO MINERAL SUN DEFENSE SPF 50- titanium dioxide, zinc oxide cream
Fallien Cosmeceuticals Ltd.

Active Ingredients:

Titanium Dioxide 10% Zinc Oxide 3%

(Purpose)

Sunscreen

Directions:

Apply liberally 15 minutes before sun exposure.

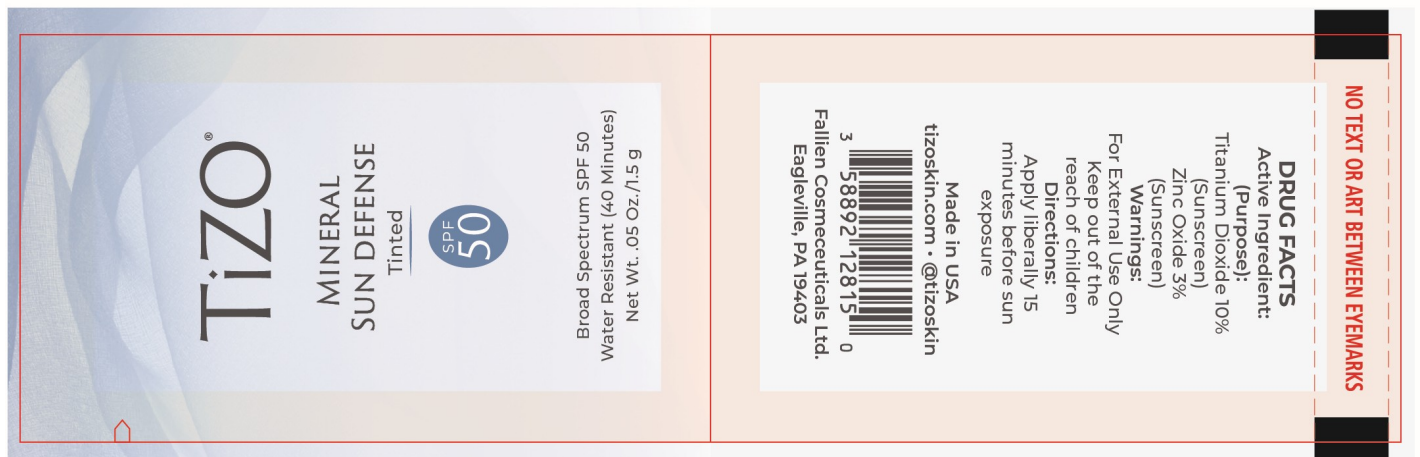
Warning and Directions:

For external use only. Apply liberally 15 minutes before sun exposure.

Warning:

For external use only.

Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Cetareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water



TIZO MINERAL SUN DEFENSE SPF 50

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
ISODODECANE (UNII: A8289P68Y2)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETEARETH-20 (UNII: YRC528SWJY)	
ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B)	
IRON OXIDES (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
TOCOPHEROL (UNII: R0ZB2556P8)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
MELISSA OFFICINALIS WHOLE (UNII: YF70189L0N)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-128-	1.5 g in 1 PACKET; Type 0: Not a Combination	03/01/2022	

15	Product	03/01/2023	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/01/2023	

Labeler - Fallien Cosmeceuticals Ltd. (958388357)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(58892-128)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-128)

Revised: 1/2025

Fallien Cosmeceuticals Ltd.