TIZO ULTRA ZINC NON-TINTED SPF 40 MINERAL SUNSCREEN FOR BODY AND FACE WITH ANTIOXIDANTS C AND E- 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.

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 am-2 pm

• 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, Hydrogren 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

• Shake well before use

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.

Keep out of the reach of children.

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging cuased by the sun.

Apply liberally 15 minutes befor sun exposure.

Principal Display Panel – 113 g Bottle Label

PROCEUTICALS

PRIVATE LABEL by TiZO

non-tinted

mineral sunscreen

20% zinc oxide

broad spectrum spf 40

water resistant (40 minutes)

net wt. 4 oz/ 113 g

Graphic-Untitled

TIZO ULTRA ZINC NON-TINTED SPF 40 MINERAL SUNSCREEN FOR BODY AND FACE WITH ANTIOXIDANTS C AND E

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58892-322
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
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE 100 (UNII: RO266O364U)	
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-322-30	30 g in 1 TUBE; Type 0: Not a Combination Product	08/09/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/09/2024	

Labeler - Fallien Cosmeceuticals, Ltd (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-322)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	pack(58892-322) , manufacture(58892-322)

Revised: 8/2024 Fallien Cosmeceuticals, Ltd