TIZO EYE RENEWAL SPF 20 (NON-TINTED)- zinc oxide cream Fallien Cosmeceuticals, LTD

Active Ingredients:

Zinc Oxide 9%

Purpose:

Sunscreen

Uses:

Helps prevents 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 reach of children. If swallowed, get medical help or contact a poison control center right away.

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:

Butylene Glycol, Caffeine, Carbomer, Caprylhydroxamic Acid, Caprylyl Glycol, Corallina Officinalis Extract, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Glycerin, Hydrogen Dimethicone, Isododecane, Isohexadecane, Lauryl PEG/PPG-18/18 Hydrogen Dimethicone, Palmitoyl Tripeptide-1, Palmitoyl Tetrapeptide-7, PEG-10 Dimethicone, Polysorbate 20, Saccharomy- ces/Selenium Ferment, Sambucus Nigra Flower Extract, Siloxanetriol Alginate, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Undaria Pinnatifida Extract, Water

Other Information:

• Protect this product from excessive heat and direct sun.

Keep out of reach of children.

Principal Display Panel - 100 g Carton Label

MINERAL PROTECTION

TIZO®

EYE RENEWAL

NON-TINTED SPF 20

Firming Eye Repair

Mineral Sunscreen

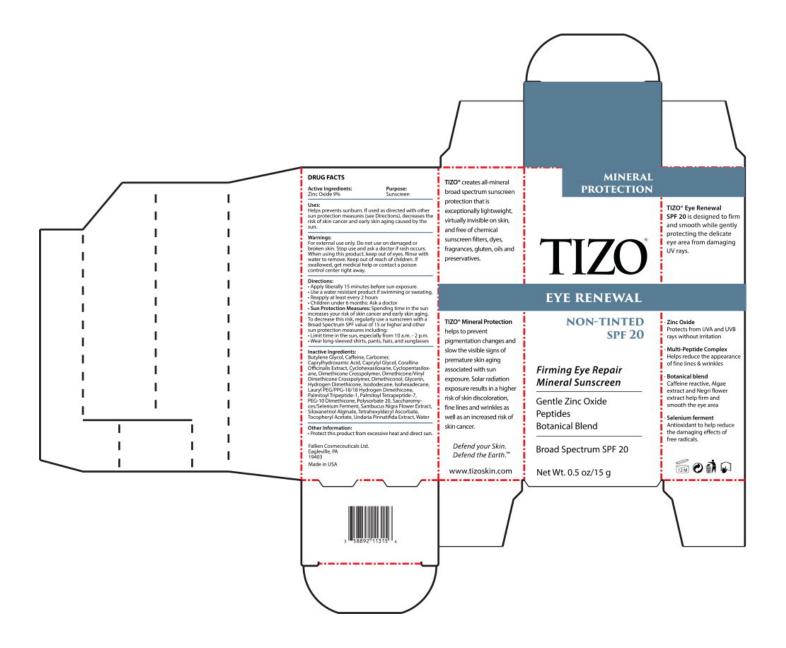
Gentle Zinc Oxide

Peptides

Botanical Blend

Broad Spectrum SPF 20

Net Wt. 0.5 oz/15 g



TIZO EYE RENEWAL SPF 20 (NON-TINTED)

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	90 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

CAFFEINE (UNII: 3G6A5W338E) **CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE** (UNII: 0A5MM307FC) CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) CAPRYLYL GLYCOL (UNII: 00YIU5438U) CORALLINA OFFICINALIS (UNII: 4004498D06) CYCLOMETHICONE 6 (UNII: XHK3U310BA) CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) DIMETHICONOL (2000 CST) (UNII: T74012AN6Y) **GLYCERIN** (UNII: PDC6A3C0OX) HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N) ISODODECANE (UNII: A8289P68Y2) **ISOHEXADECANE** (UNII: 918X1OUF1E) LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX) PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M) PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R) PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) POLYSORBATE 20 (UNII: 7T1F30V5YH) SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H) SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T) **SILANETRIOL** (UNII: E52D0J3TS5) TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) UNDARIA PINNATIFIDA (UNII: ICV10K7M1S) WATER (UNII: 059QF0KO0R)

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:58892- 113-15	1 in 1 CARTON	09/01/2020		
1		15 g in 1 BOTTLE, PUMP; 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	09/01/2020	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis (58892-113)

Establishment				
Name	Address	ID/FEI	Business Operations	
Fragrance Manufacturing Inc. (FMI)		793406000	manufacture(58892-113), pack(58892-113)	

Revised: 10/2024 Fallien Cosmeceuticals, LTD