

TIZO EYE RENEWAL SPF 20 (NON-TINTED)- 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 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, Saccharomyces/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.

Principal Display Panel - 100 g Carton Label

**MINERAL
PROTECTION**

TIZO®

EYE RENEWAL

**NON-TINTED
SPF 20**

Firming Eye Repair

Mineral Sunscreen

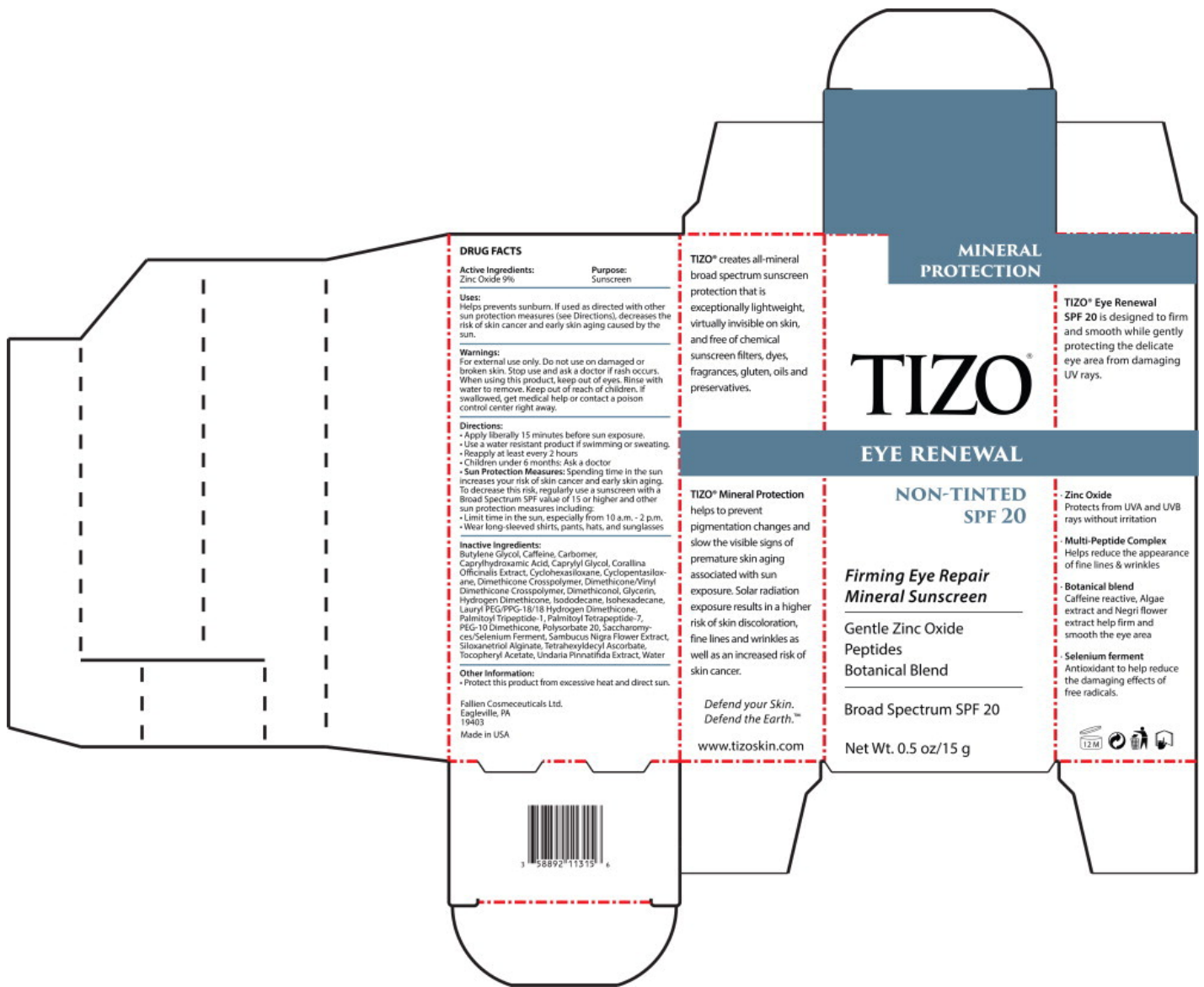
Gentle Zinc Oxide

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: T74O12AN6Y)
Glycerin (UNII: PDC6A3C00X)
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: ICV1OK7M1S)
Water (UNII: 059QF0KO0R)

Packaging

#	Item 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 not final	part352	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: 1/2022

Fallien Cosmeceuticals, LTD