

**PROCEUTICALS PRIVATE LABEL BY TIZO EYE REPAIR NON-TINTED MINERAL
SUNSCREEN- zinc oxide cream
Fallien Cosmeceuticals, LTD**

ACTIVE INGREDIENT: Zinc Oxide 9%

PURPOSE: Sunscreen

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 am - 2 pm • 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 Methicone, 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

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.

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 caused by the sun.

Apply liberally 15 minutes before sun exposure.

Principal Display Panel – 15 g Bottle Label

Proceuticals

PRIVATE LABEL by TiZO

eye repair non-tinted
mineral sunscreen

broad spectrum spf 20 with
gentle zinc oxide, peptides
& botanical blend

net wt. 0.5 oz. / 15 g

Graphic-Untitled

DRUG FACTS

ACTIVE INGREDIENT: Zinc Oxide 9%
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 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 am - 2 pm · 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 Methicone, 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

MANUFACTURED FOR:
City, State, Zip

NDC 58892-236-05

net wt. 0.5 oz. /15 g



PROCEUTICALS
PRIVATE LABEL by TIZO

eye repair non-tinted
mineral sunscreen

broad spectrum spf 20 with
gentle zinc oxide, peptides
& botanical blend

PROCEUTICALS PRIVATE LABEL BY TIZO EYE REPAIR NON-TINTED MINERAL SUNSCREEN

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-236
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
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CORALLINA OFFICINALIS (UNII: 4004498D06)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SILANETRIOL (UNII: E52D0J3TS5)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
UNDARIA PINNATIFIDA (UNII: ICV1OK7M1S)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAFFEINE (UNII: 3G6A5W338E)	
ISODODECANE (UNII: A8289P68Y2)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
WATER (UNII: 059QF0K00R)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-236-05	15 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/27/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/27/2024	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-236)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	pack(58892-236) , manufacture(58892-236)

Revised: 9/2024

Fallien Cosmeceuticals, LTD