

**PROCEUTICALS PRIVATE LABEL BY TIZO TINTED REPLENISHING DAILY
PROTECTION- zinc oxide cream
Fallien Cosmeceuticals, Ltd**

ACTIVE INGREDIENT: Zinc Oxide 16%

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: Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

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 caused by the sun.

Apply liberally 15 minutes before sun exposure.

Principal Display Panel – 50g Bottle Label

PROCEUTICALS

PRIVATE LABEL by TiZO

tinted replenishing
daily protection

broad spectrum spf 40
with ceramides, zinc oxide
& antioxidants C & E

net wt. 1.75 oz / 50 g

Graphic-Untitled

DRUG FACTS

ACTIVE INGREDIENT:
Zinc Oxide 16%

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:

Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

MANUFACTURED FOR:
City, State, Zip

NDC 58892-208-50



PROCEUTICALS
PRIVATE LABEL by TiZO

tinted replenishing
daily protection

broad spectrum spf 40
with ceramides, zinc oxide
& antioxidants C & E

net wt. 1.75 oz / 50 g

PROCEUTICALS PRIVATE LABEL BY TIZO TINTED REPLENISHING DAILY PROTECTION

zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58892-208

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONE 20 (UNII: H8YMB5QY0D)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CERAMIDE 3 (UNII: 4370DF050B)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/08/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/08/2024	

Labeler - Fallien Cosmeceuticals, Ltd (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	manufacture(58892-208) , pack(58892-208)

Revised: 7/2024

Fallien Cosmeceuticals, Ltd