

**PROCEUTICALS PRIVATE LABEL BY TIZO DAILY DEFENSE TINTED MINERAL  
SUNSCREEN- titanium dioxide, zinc oxide cream  
Fallien Cosmeceuticals, LTD**

-----  
**ACTIVE INGREDIENTS:**

Titanium Dioxide 10%

Zinc Oxide 3%

**PURPOSE:**Sunscreen

**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:**

Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Ceteareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water

**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 – 53 g Bottle Label

Proceuticals

PRIVATE LABEL by TIZO

daily defense tinted  
mineral sunscreen

broad spectrum spf 50  
water resistant (40 minutes)

net wt. 1.8 oz / 53 g

Graphic-Untitled

### DRUG FACTS

#### ACTIVE INGREDIENTS:

Titanium Dioxide 10%  
Zinc Oxide 3%

#### PURPOSE:

Sunscreen  
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.

#### 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.

#### 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:

Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Cetareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, Triethanolamine, Triethoxycaprylylsilane, Water

#### OTHER INFORMATION:

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

MANUFACTURED FOR:  
City, State, Zip

NDC 58892-258-50

net wt. 1.8 oz / 53 g



**PROCEUTICALS**  
PRIVATE LABEL by TIZO

daily defense tinted  
mineral sunscreen

broad spectrum spf 50  
water resistant (40 minutes)

## PROCEUTICALS PRIVATE LABEL BY TIZO DAILY DEFENSE TINTED MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:58892-258

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30 mg in 1 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	100 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)	
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>ETHYLHEXYL HYDROXYSTEARATE BENZOATE</b> (UNII: 3W8F25684B)	
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>MELISSA OFFICINALIS WHOLE</b> (UNII: YF70189L0N)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW)</b> (UNII: 9713Q0S7FO)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-258-50	53 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(58892-258)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	pack(58892-258) , manufacture(58892-258)

Revised: 7/2024

Fallien Cosmeceuticals, LTD