

**PROCEUTICALS PRIVATE LABEL BY TIZO MINERAL LIP SUNSCREEN- titanium dioxide, zinc oxide stick**  
**Fallien Cosmeceuticals, LTD**

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**ACTIVE INGREDIENTS:**

Titanium Dioxide 4%

Zinc Oxide 5.5%

**PURPOSE:**Sunscreen

**DIRECTIONS:**

- Apply liberally 15 minutes before sun exposure.
- Reapply:
  - After 80 minutes of swimming or sweating
  - Immediately after towel drying
  - At least every 2 hours
- Children under 6 months: Ask a doctor

**INACTIVE INGREDIENTS:**

Alumina, Aluminum Hydroxide, Aluminum Stearate, Asorbic Acid, Ascorbyl Palmitate, C Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Dipropylene Glycol Dicaprylate-Caprate. Ethylhexyl Palmitate, Flavor, Helianthus Annuus (Sunflower) Seed Wax, Hexyldecanol, Hexyldecyl Laurate, Iron Oxide, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Disostearate, Polyhydroxystearic Acid, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oi

**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. 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

non-tinted

mineral sunscreen

broad spectrum spf 40

water resistant (80 minutes)

net wt. 1.8 oz / 53 g

Graphic-Untitled



**PROCEUTICALS**  
PRIVATE LABEL by TIZO

## mineral lip sunscreen

broad spectrum spf 45  
water resistant (80 minutes)

net wt. .14 oz /4.5 g

**DRUG FACTS:**

**ACTIVE INGREDIENTS:** Titanium Dioxide 4.0%, Sunscreen, Zinc  
**PURPOSE:** Sunscreen

**USES:** Helps prevent sunburn. If used as directed with other sun  
(see directions), decreases the risk of skin cancer and early skin ag

**WARNINGS:** For external use only. Do not use on damaged or l  
and ask a doctor if rash occurs. When using this product, keep  
water to remove. **Keep out of the reach of children.** Get medic  
Poison Control Center right away.

**DIRECTIONS:** Apply liberally 15 minutes before sun exposure. R  
minutes of swimming or sweating, immediately after towel dry.  
2 hours • Children under 6 months: Ask a doctor

**INACTIVE INGREDIENTS:** Alumina, Aluminum Hydroxide, Aluminum  
Ascorbyl Palmitate, C12-15 Alkyl Benzoate, Cetearyl Isocrotonate, Cetyl  
Ether Dimethicone, Citric Acid, Ethylhexyl Palmitate, Flavor, Helianthus  
Hexyldecanol, Hexyldecyl Laurate, Iron Oxide, Lecithin, Ozokerite, PEG-8  
Diisostearate, Polyhydroxystearic Acid, Propylene Glycol Dicaprylate/Dic  
Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

**MANUFACTURED FOR:** City, State, Zip

### PROCEUTICALS PRIVATE LABEL BY TIZO MINERAL LIP SUNSCREEN

titanium dioxide, zinc oxide stick

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58892-212
<b>Route of Administration</b>	TOPICAL		

#### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	55 mg in 1 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LECITHIN, SUNFLOWER (UNII: 834K0W0S5G)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
DIPROPYLENE GLYCOL CAPRYLATE (UNII: CJ981S4H3T)	
KIWI FRUIT OIL (UNII: 66086CWP3Q)	
HEXYLDECANOL (UNII: 151Z7P1317)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CITRUS AURANTIIFOLIA FRUIT OIL (UNII: 7937R189CB)	
CERESIN (UNII: Q1LS2UJO3A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GINGER OIL (UNII: SAS9Z1SVUK)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-212-45	4.5 g in 1 TUBE; Type 0: Not a Combination Product	07/16/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/16/2024	

**Labeler** - Fallien Cosmeceuticals, LTD (958388357)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-212)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	pack(58892-212) , manufacture(58892-212)

Revised: 7/2024

Fallien Cosmeceuticals, LTD