

**PROCEUTICALS PRIVATE LABEL BY TIZO NON-TINTED MINERAL SUNSCREEN
STICK- titanium dioxide, zinc oxide stick
Fallien Cosmeceuticals, Ltd**

ACTIVE INGREDIENTS:

Titanium Dioxide 4.0%

Zinc Oxide 5.5%

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:DIRECTIONS: Apply liberally 15 minutes before sun exposure. Reapply: • After 80 minutes of swimming or sweating • Immediately after towel drying • 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: Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbic Acid, Ascorbyl Palmitate, C12-15 Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Ethylene Brassylate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Wax, Hexyldecanol, Hexyldecyl Laurate, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Propylene Glycol Dicaprylate/Dicaprate, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

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 the reach of children. If swallowed, get medical help or contact a Poison Control

Center right away.

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Principal Display Panel - 30g Cylinder Label

PROCEUTICALS

PRIVATE LABEL by TiZO

non-tinted mineral

sunscreen stick

broad spectrum spf 45
water resistant (80 minutes)

Net Wt. 1 oz. /30 g

Graphic-Untitled

DRUG FACTS (continued)

INACTIVE INGREDIENTS: Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbic Acid, Ascorbyl Palmitate, C12-15 Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Ethylene Brassylate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Wax, Hexyldecanol, Hexyldecyl Laurate, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Propylene Glycol Dicaprylate/Dicaprate, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

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NDC 58892-219-30

MANUFACTURED FOR:
City, State, Zip



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PRIVATE LABEL by TiZO

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sunscreen stick

broad spectrum spf 45
water resistant (80 minutes)

Net Wt. 1 oz. /30 g

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titanium dioxide, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-219
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
CERESIN (UNII: Q1LS2UJO3A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HEXYLDECANOL (UNII: 151Z7P1317)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GINGER OIL (UNII: SAS9Z1SVUK)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIPROPYLENE GLYCOL CAPRYLATE (UNII: CJ981S4H3T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-219-30	30 g in 1 CYLINDER; Type 0: Not a Combination Product	08/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/30/2024	

Labeler - Fallien Cosmeceuticals, Ltd (958388357)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	manufacture(58892-219)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-219)

Revised: 8/2024

Fallien Cosmeceuticals, Ltd