

TIZO ULTRA ZINC SPF 40 (NON-TINTED)- zinc oxide cream
Fallien Cosmeceuticals, LTD

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DRUG FACTS

Active Ingredients:

Zinc Oxide 20%

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.

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:

C₁₂₋₁₅ Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

Other Information:

- Protect this product from excessive heat and direct sun
- **Shake well before use**

Principal Display Panel -100g Carton Label**TiZO®**

ULTRA ZINC

Non-Tinted

SPF
40**MINERAL SUNSCREEN****FOR BODY & FACE**

20% Zinc Oxide

Antioxidants C & E

Moisturizing

Broad Spectrum SPF 40

Water Resistant (40 minutes)

Net Wt. 3.5 Oz./ 100g

TiZO®
ULTRA ZINC
Non-Tinted

DRUG FACTS

Active Ingredients: Zinc Oxide 20%
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.

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:

C₁₂₋₁₅ Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

Other Information:

• Protect this product from excessive heat and direct sun • **Shake well before use**

TiZO® creates all-mineral broad spectrum sunscreen protection that is exceptionally lightweight, virtually invisible on skin, and 100% free of chemical sunscreen filters, dyes, fragrances, gluten and preservatives.



ALL-MINERAL
SUNSCREEN



PRESERVATIVE FREE



ANTIOXIDANTS C & E



REEF FRIENDLY



DEFEND YOUR SKIN.
DEFEND THE EARTH.



@tizoskin
tizoskin.com

TiZO®

ULTRA ZINC
Non-Tinted

SPF
40

MINERAL SUNSCREEN
FOR BODY & FACE

20% Zinc Oxide
Antioxidants C & E
Moisturizing

Broad Spectrum SPF 40
Water Resistant (40 Minutes)
Net Wt. 3.5 Oz./100 g

TiZO Ultra Zinc Body & Face Sunscreen is a moisturizing all-mineral sunscreen suitable for all skin types and tones. Sheer and virtually invisible, it smooths onto the skin, leaving a soft, elegant finish.

• 20% Zinc Oxide formula calms and soothes

• Non-tinted

• Gentle protection that is ideal for post-procedure use and sensitive skin

• **FREE** of chemical sunscreen filters, dyes, fragrances, oils and preservatives

Age Defying Fusion®

When used regularly, TiZO Ultra Zinc Body & Face Sunscreen helps to decrease the risk of skin cancer and early skin aging caused by the sun.

Fallien Cosmeceuticals Ltd.

Eagleville, PA 19403

Made in USA



3 58892 31701 1

Principal Display Panel -100g Tube Label

TiZO®

ULTRA ZINC

Non-Tinted

SPF

**MINERAL SUNSCREEN
FOR BODY & FACE**

With Antioxidants C & E

Broad Spectrum SPF 40

Water Resistant (40 minutes)

Net Wt. 3.5 Oz./ 100g

TIZO[®]

ULTRA ZINC
Non-Tinted

SPF
40

**MINERAL SUNSCREEN
FOR BODY & FACE**

With Antioxidants C & E

Broad Spectrum SPF 40
Water Resistant (40 Minutes)
Net Wt. 3.5 Oz./100 g

DRUG FACTS

Active Ingredients: Zinc Oxide 20% **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.

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 a.m.-2 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses

Other Information:
• Protect this product from excessive heat and direct sun • **Shake well before use**

Fallien Cosmeceuticals, Ltd.
Eagleville, PA 19403
Made in USA
www.tizoskin.com

12 M ♻️ ♻️ ♻️ ♻️ 3 58892 31701 1

Minimum = 5MM

TIZO ULTRA ZINC SPF 40 (NON-TINTED)

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-317
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE 100 (UNII: RO266O364U)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-317-01	1 in 1 CARTON	03/15/2022	
1		100 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/15/2015	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(58892-317)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-317) , PACK(58892-317)

Revised: 4/2022

Fallien Cosmeceuticals, LTD