

TIZO2- titanium dioxide, 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:

Titanium Dioxide 8%

Zinc Oxide 3.8%

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 80 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 lime in the sun, especially from 10 am-2 pm

- Wear long-sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients:

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

Other Information:

- Protect this product from excessive heat and direct sun

Principal Display Panel - 50 g Carton Label**TiZO[®]₂**

PRIMER/
SUNSCREEN

Non-Tinted

SPF
40

PA++++

**FACIAL
MINERAL SUNSCREEN**

Titanium & Zinc Oxides

Antioxidants C & E

Sheer Matte Finish

Broad Spectrum SPF 40

Water Resistant (80 Minutes)

Net Wt. 1.75 Oz./50 g

TiZO[®]₂
PRIMER/SUNSCREEN
Non-Tinted

DRUG FACTS

| | |
|----------------------------|----------------|
| Active Ingredients: | Purpose |
| Titanium Dioxide 8% | Sunscreen |
| Zinc Oxide 3.8% | 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 80 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:

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahydrodecyl Ascorbate, Tocopheryl Acetate

Other Information:

· Protect this product from excessive heat and direct sun

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[™]



TiZO[®]₂

PRIMER/
SUNSCREEN
Non-Tinted

SPF
40

PA++++

FACIAL
MINERAL SUNSCREEN

Titanium & Zinc Oxides
Antioxidants C & E
Sheer Matte Finish

Broad Spectrum SPF 40
Water Resistant (80 Minutes)
Net Wt. 1.75 Oz./50 g

TiZO₂ is a sheer facial mineral sunscreen that offers cosmetically elegant broad spectrum sun protection with a matte finish. TiZO₂ may be used alone or layered invisibly to replace makeup primer.

- Non-tinted
- Gentle on ALL skin types, even sensitive; great for post procedure use
- **FREE** of chemical sunscreen filters, dyes, fragrances, oils and preservatives
- Reef Friendly

Age Defying Fusion[®]
When used regularly, TiZO₂ 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



Principal Display Panel - 50 g Tube Label

TiZO[®]₂

PRIMER/

SUNSCREEN

Non-Tinted

SPF
40

PA++++

FACIAL MINERAL SUNSCREEN

With Antioxidants C & E

Broad Spectrum SPF 40

Water Resistant (80 Minutes)

Net Wt. 1.75 Oz./50 g

TiZO₂[®]

PRIMER/ SUNSCREEN

Non-Tinted

SPF
40

PA++++

FACIAL MINERAL SUNSCREEN

With Antioxidants C & E

Broad Spectrum SPF 40
Water Resistant (80 Minutes)
Net Wt. 1.75 Oz./50 g

DRUG FACTS

Active Ingredients:
Titanium Dioxide 8%
Zinc Oxide 3.8%

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 80 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

Fallien Cosmeceuticals, Ltd.

Eagleville, PA 19403

Made in USA

www.tizoskin.com



TIZO2

titanium dioxide, zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58892-336

| | |
|--------------------------------|---------|
| Route of Administration | TOPICAL |
|--------------------------------|---------|

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP) | Titanium Dioxide | 85.4 mg in 1 mL |
| Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) | Zinc Oxide | 40.7 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| Aluminum Hydroxide (UNII: 5QB0T2IUN0) | |
| Cyclomethicone 6 (UNII: XHK3U310BA) | |
| Cyclomethicone 5 (UNII: 0THT5PCI0R) | |
| Dimethicone 20 (UNII: H8YMB5QY0D) | |
| Dimethicone Crosspolymer (450000 MPA.S AT 12% in Cyclopentasiloxane) (UNII: UF7620L1W6) | |
| Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4CO0W6C5) | |
| Dimethiconol (2000 CST) (UNII: T74O12AN6Y) | |
| Lauryl PEG/PPG-18/18 Methicone (UNII: ZJ5S27D9NX) | |
| Hydrogen Dimethicone (20 CST) (UNII: 12Z59IF64N) | |
| PEG-10 Dimethicone (600 CST) (UNII: 8PR7V1SVM0) | |
| Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ) | |
| .Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:58892-336-50 | 1 in 1 CARTON | 04/27/2015 | |
| 1 | | 50 mL 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 | 02/19/2009 | |

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | ANALYSIS(58892-336) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------------|---------|-----------|--|
| Fragrance Manufacturing Inc. (FMI) | | 793406000 | MANUFACTURE(58892-336) , PACK(58892-336) |

Revised: 10/2019

Fallien Cosmeceuticals, LTD