

TIZO ULTRA NON TINTED MINERAL SUNSCREEN- zinc oxide 20% lotion
Fallien Cosmeceuticals, LTD

TIZO ULTRA NON TINTED MINERAL SUNSCREEN 3.5OZ (IS0385)

Zinc Oxide 20% 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.

When using this product ■ keep out of eyes. Rinse eyes with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children.

If swallowed, get medical help or contact a Polson 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. **Sun protection measures:** Spending time In the sun Increases your risk of skin cancer and early skin aging. To decrease risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures Including: ■ limit time In the sun, especally from 10am to 2pm ■ wear long-sleeved shirts, pants, hats, and sunglasses ■ children under 6 months: ask a doctor ■ do not spray directly Into face. Spray on hands then apply to face ■ use In well-ventilated area.




Other information

protect this product from excessive heat and direct sun ■ may stain fabrics.

Inactive Ingredients

Cyclopentasiloxane
Dimethicone Crosspolymer
Cyclopentasiloxane
Cyclohexasiloxane
Cyclopentasiloxane
Dimethiconol
Stearyl Dimethicone
Octadecene
Dimethicone
Polyglyceryl-4 Isostearate
Cetyl PEG/PPG-10/1 Dimethicone
PEG-30 Dipolyhydroxystearate
Tetrahexyldecyl Ascorbate
Tocopheryl Acetate
C12-15 Alkyl Benzoate
Microcrystalline Wax
Caprylhydroxamic Acid
Caprylyl Glycol
Glycerin

Disodium EDTA
Sodium Chloride
Polysorbate 20
Triethanolamine
Water

<p>DRUG FACTS Active Ingredients: Zinc Oxide 20% Purpose: Sunscreen</p> <p>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.</p> <p>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.</p> <p>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</p> <p>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</p> <p>Other Information: • Protect this product from excessive heat and direct sun • Shake well before use</p>	<p>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.</p> <p> ALL-MINERAL SUNSCREEN</p> <p> PRESERVATIVE FREE</p> <p> ANTIOXIDANTS C & E</p> <p> REEF FRIENDLY</p> <p> ANIMAL TEST-FREE VEGAN</p> <p> DEPEND YOUR SKIN. DEFEND THE EARTH™</p> <p> @tizoskin tizoskin.com</p>	 <p>TIZO®</p> <p>ULTRA ZINC Non-Tinted SPF 40</p> <p>MINERAL SUNSCREEN FOR BODY & FACE</p> <p>20% Zinc Oxide Antioxidants C & E Moisturizing</p> <p>Broad Spectrum SPF 40 Water Resistant (40 Minutes) Net Wt. 3.5 Oz./100 g</p>	<p>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.</p> <ul style="list-style-type: none"> • 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 <p>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.</p> <p>Fallien Cosmeceuticals Ltd. Eagleville, PA 19403 Made in USA</p> <p></p>
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TIZO ULTRA NON TINTED MINERAL SUNSCREEN

zinc oxide 20% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-072
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (ETHYLHEXYL SALICYLATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALCOHOL (UNII: 3K9958V90M)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
ORYZA SATIVA (RICE) SEED OIL (UNII: ACU8G2V809)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-072-04	100 g in 1 TUBE; Type 0: Not a Combination Product	08/21/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/21/2025	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Registrant - Inspec Solutions LLC (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC		081030372	manufacture(58892-072)

Revised: 5/2026

Fallien Cosmeceuticals, LTD