

TIZO PHOTOCEUTICAL ENVIRONMENTAL SKIN PROTECTANT- dimethicone gel
Fallien Cosmeceuticals, LTD

DRUG FACTS

Active Ingredients:

Dimethicone 3%

Purpose:

Skin Protectant

Uses:

- Temporarily protects and helps relieve chapped or cracked skin.
- Helps protect from the drying effects of wind and cold weather.

Warnings:

- ***For external use only.***

Do not use on:

- deep puncture wounds
- animal bites
- serious burns

When using this product:

- Do not get into eyes

Stop use and ask doctor if:

- Condition worsens
- Symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach out children.

If swallowed, get medical help or contact a poison control center right away.

Directions:

- Gently cleanse and dry affected area
- Apply liberally to affected area as needed

Inactive Ingredients:

Bisabolol, Caprylhydroxamic Acid, Caprylyl Glycol, Ceramide 3, Copper PCA Methylsilanol, Cydohexasiloxane, Cyclopentasiloxane, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Glycerin, Isohexadecane, Isononyl

Isononanoate, Lauryl PEG/PPG-18/18 Hydrogen Dimethicone, Propyl Gallate, Polysorbate 20, Saccharomyces/ Copper Ferment, Tetrahexyldecyl Ascorbate, Tocopherol, Tocopheryl Acetate, Vinyl Dimethicone/Hydrogen Dimethicone Silsesquioxane Crosspolymer, Water

Keep out of the reach of children.

Principal Display Panel - Carton Label

ENVIRONMENTAL

SKIN PROTECTANT

TIZO®

PHOTOCEUTICAL®

***Especially effective against
environmental damage***

Dimethicone 3%

Copper Peptides

Bisabolol

featuring

SKIN FIRM TECHNOLOGY®

1 Fl. Oz./29 ml



Principal Display Panel - Bottle Label

TIZO®

PHOTOCEUTICAL®

**ENVIRONMENTAL
SKIN PROTECTANT**

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Copper Peptides

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SKIN FIRM TECHNOLOGY®

1 Fl. Oz./29 ml

<p>Active Ingredients: Dimethicone 3%</p> <p>Purpose: Skin Protectant</p> <p>Uses:</p> <ul style="list-style-type: none">• Temporarily protects and helps relieve chapped or cracked skin.• Helps protect from the drying effects of wind & cold weather. <p>Warnings:</p> <ul style="list-style-type: none">• For external use only. <p>Do not use on:</p> <ul style="list-style-type: none">• deep puncture wounds• serious burns• animal bites <p>When using this product:</p> <ul style="list-style-type: none">• Do not get into eyes <p>Stop use and ask doctor if:</p> <ul style="list-style-type: none">• Condition worsens• Symptoms last more than 7 days or clear up and occur again within a few days <p>Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.</p> <p>Directions:</p> <ul style="list-style-type: none">• Gently cleanse and dry affected area• Apply liberally to affected area as needed	<h1>TIZO®</h1> <h2>PHOTOCEUTICAL®</h2> <h3>ENVIRONMENTAL SKIN PROTECTANT</h3> <hr/> <p>Dimethicone 3% Copper Peptides Bisabolol</p> <hr/> <p>featuring SKIN FIRM TECHNOLOGY®</p> <p>1 Fl. Oz./29 ml</p>	<p>Inactive Ingredients: Bisabolol, Caprylhydroxamic Acid, Caprylyl Glycol, Ceramide 3, Copper PCA Methylsilanol, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Glycerin, Isohexadecane, Isononyl Isononanoate, Lauryl PEG/PPG-18/18 Hydrogen Dimethicone, Propyl Gallate, Polysorbate 20, Saccharomyces/ Copper Ferment, Tetrahexyldecyl Ascorbate, Tocopherol, Tocopheryl Acetate, Vinyl Dimethicone/ Hydrogen Dimethicone Silsesquioxane Crosspolymer, Water</p> <p>Fallien Cosmeceuticals Ltd. Eagleville, PA 19403 Made in USA www.tizofusion.com</p>
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TIZO PHOTOCEUTICAL ENVIRONMENTAL SKIN PROTECTANT

dimethicone gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58892-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE NP (UNII: 4370DF050B)	
COPPER PIDOLATE (UNII: 497G7G1SL1)	
METHYLSILANOL PCA (UNII: 837430510V)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58892-105-30	1 in 1 CARTON	07/23/2019	
1		29 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/20/2018	

Labeler - Fallien Cosmeceuticals, LTD (958388357)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(58892-105)

Establishment

Name	Address	ID/FEI	Business Operations
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Fragrance Manufacturing Inc. (FMI)

793406000

manufacture(58892-105) , pack(58892-105)

Revised: 11/2024

Fallien Cosmeceuticals, LTD