

TIZO PHOTOCEUTICAL ENVIRONMENTAL SKIN PROTECTANT- dimethicone gel
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:

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

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

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PHOTOCEUTICAL®

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

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: 36HQ158VC)	
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: 0TH5PC10R)
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
GLYCERIN (UNII: PDC6A3C0OX)
ISOHEXADECANE (UNII: 918X10UF1E)
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: 9LVB3F07AZ)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)
WATER (UNII: 059QF0K00R)

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 final	part352	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
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(58892-105) , PACK(58892-105)