

**ANTIOXIDANT SPF- zinc oxide cream**  
**Teton Dermatology Holdings, Inc.**

**DRUG FACTS (cont)**

• **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 sleeve shirts and hats and sunglasses

**INACTIVE INGREDIENTS:**

Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Hydrogen Dimethicone Silsesquioxane Crosspolymer

**OTHER INFORMATION:**

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

**Teton Dermatology**  
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**307-734-1800**  
**tetondermatology.com**



**TETON  
 DERMATOLOGY**

*Medical, Surgical & Cosmetic Skin Care*

**Antioxidant  
 SPF 40  
 Broad Spectrum**

with Antioxidant Vitamins C & E,  
 Ceramides & Zinc Oxide

FREE OF CHEMICAL SUNSCREENS  
 & PARABENS

NET WT 1.75 oz/ 50 g

**DRUG FACTS**

**ACTIVE INGREDIENT:** Zinc Oxide 16%      **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 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 reach of children. If swallowed, get medical help or contact a poison control center right away.

**DIRECTIONS:**

- Apply liberally 15 minutes before sun exposure
- Use a water resistant product if swimming or sweating.
- Reapply at least every 2 hours
- Children under 6 months: Ask a doctor

**ANTIOXIDANT SPF**

zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85339-208(NDC:58892-208)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
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<b>CI 77499</b> (UNII: XM0M87F357)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>CI 77492</b> (UNII: EX438O2MRT)
<b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)
<b>CI 77491</b> (UNII: 1K09F3G675)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>CERAMIDE 3</b> (UNII: 4370DF050B)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85339-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/27/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/27/2023	

**Labeler** - Teton Dermatology Holdings, Inc. (078310619)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85339-208)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85339-208)

### Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85339-208)