

**NON-TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream**  
**R. Sonia Batra, MD, 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-sleeved shirts, pants, hats, and sunglasses

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

**OTHER INFORMATION:**

- Protect this product from excessive heat and direct sun
- May stain some fabrics
- Cleanse thoroughly at nighttime
- PA ++++

**MANUFACTURED FOR:**

Batra Medical, Surgical and Cosmetic Demotology  
 Santa Monica, CA 90404  
 Batraskincare.com  
 (301) 829-9099

**batra**  
 medical, surgical, and  
 cosmetic dermatology

**Non-Tinted  
 Mineral Sunscreen**

**SPF 40  
 Broad Spectrum**

**Water Resistant (80 minutes)**

**Net Wt. 1.8 oz./53 g.**

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**NON-TINTED MINERAL SUNSCREEN**

titanium dioxide, zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85359-202(NDC:58892-202)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	80 mg in 1 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	38 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>ALUMINA</b> (UNII: LMI26O6933)	
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)	
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)	
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)	
<b>LAURYL PEG/PPG-18/18 METHICONE</b> (UNII: ZJ5S27D9NX)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85359-202-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/22/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/22/2020	

**Labeler** - R. Sonia Batra, MD, Inc. (010628771)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85359-202)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85359-202)

### Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85359-202)

Revised: 12/2025

R. Sonia Batra, MD, Inc.