

**PRIIA TINTED MINERAL SUNSCREEN AND PRIMER- titanium dioxide, zinc oxide cream**  
**Priia Cosmetics Inc**

*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.*

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**DRUG FACTS**

**ACTIVE INGREDIENTS:**

Titanium Dioxide 8%

Zinc Oxide 3.8%

**PURPOSE:**

Sunscreen

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.

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.

**DIRECTIONS:**

- Apply liberally 15 minutes before sun exposure.
- Reapply:
  - After 80 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

#### **INACTIVE INGREDIENTS:**

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide (CI77491), Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

#### **OTHER INFORMATION:**

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

Manufactured for  
PRIIA® Cosmetics,  
Bethlehem PA 18020  
PRIIA.com

#### **Principal Display Panel - 85g Bottle Label**

**PRIIA®**

minerale-derm

Tinted Mineral  
Sunscreen + Primer

SPF 40

Broad Spectrum

Water Resistant  
(80 Minutes)

Acne-Safe

Net Wt. 3 oz/85 g

**DRUG FACTS (cont)**

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Vegan  
Cruelty-free  
Paraben-free  
Non-Comedogenic  
Non-Acneogenic

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minerale-derm

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titanium dioxide, zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81493-201
<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>Aluminum Hydroxide</b> (UNII: 5QB0T2IUN0)	
<b>Cyclomethicone 6</b> (UNII: XHK3U310BA)	

<b>Cyclomethicone 5</b> (UNII: 0THT5PCI0R)	
<b>Dimethicone 20</b> (UNII: H8YMB5QY0D)	
<b>Dimethicone Crosspolymer (450000 MPA.S AT 12% in Cyclopentasiloxane)</b> (UNII: UF7620L1W6)	
<b>Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle)</b> (UNII: 9E4CO0W6C5)	
<b>Dimethiconol (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>Brown Iron Oxide</b> (UNII: 1N032N7MFO)	
<b>Lauryl PEG/PPG-18/18 Methicone</b> (UNII: ZJ5S27D9NX)	
<b>Hydrogen Dimethicone (20 CST)</b> (UNII: 12Z59IF64N)	
<b>PEG-10 Dimethicone (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>Tetrahexyldecyl Ascorbate</b> (UNII: 9LBV3F07AZ)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81493-201-80	85 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/22/2022	

**Labeler** - Priia Cosmetics Inc (117845014)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(81493-201)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(81493-201) , PACK(81493-201)

Revised: 2/2023

Priia Cosmetics Inc