

## **MEDIUM DARK FOUNDATION SPF 15 - titanium dioxide, zinc oxide powder**

**Bare Escentuals Beauty 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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### **BareMineral Original SPF 15 Foundation Medium Dark**

#### **Drug Facts**

##### **Active Ingredients**

Zinc Oxide 20%

Titanium Dioxide 7%

##### **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**

- Skin cancer/skin aging alert: spending time in the sun increases your risk of cancer and early aging
- This product has been shown only to help prevent sunburn, not skin cancer or early aging
- **For External use only**
- Do not use on damage or broken skin
- When using this product keep out of eyes. Rinse with water to remove
- **Stop use and ask doctor if** rash occurs
- **Keep out of reach of children**
- If product is swallowed get medical help or contact a poison control center right away

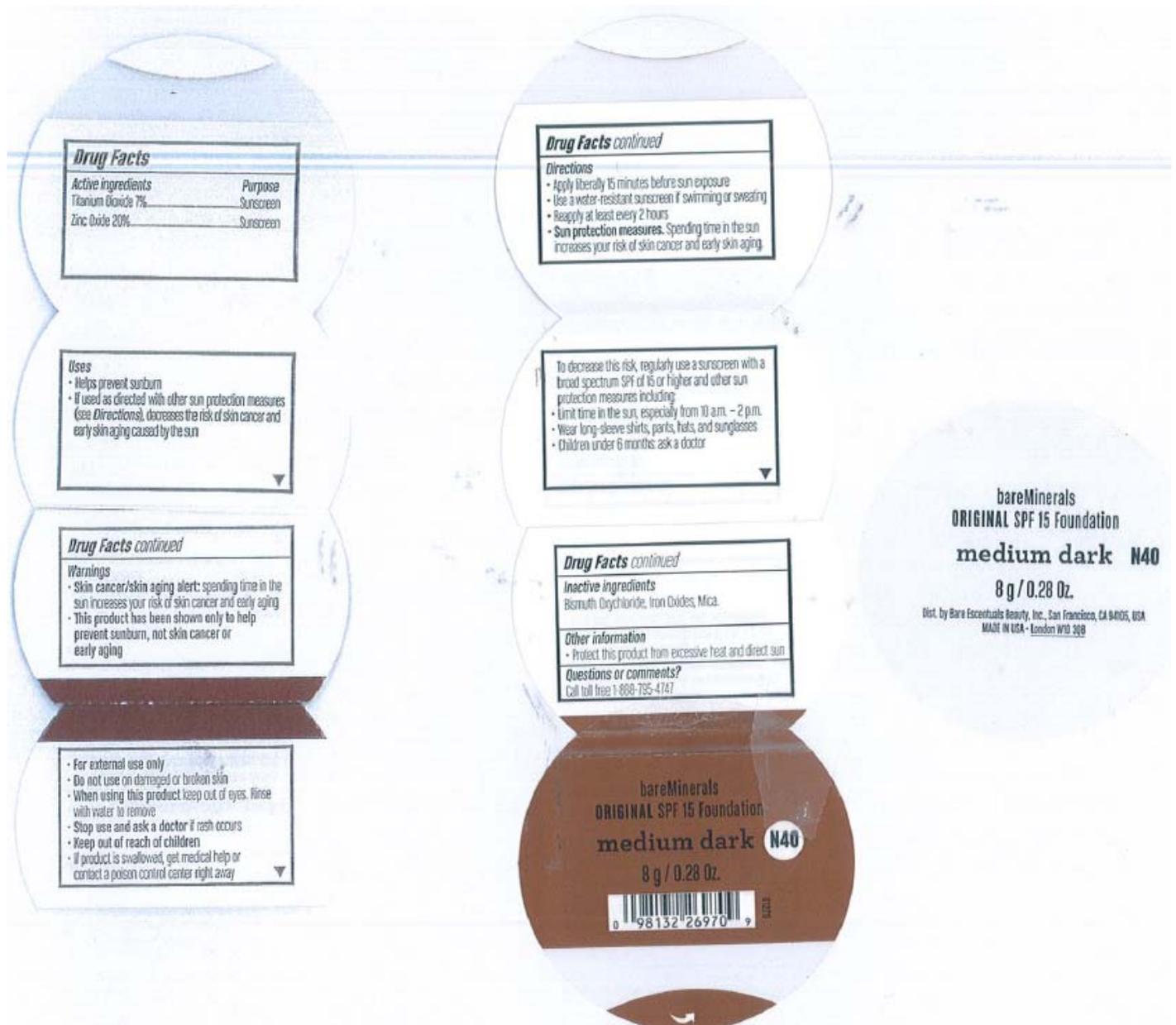
##### **Directions**

- Apply liberally 15 minutes before sun exposure
- Use a water-resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- **Sun protection measures.** Spending time in the sun increases your risk of skin cancer or early skin aging. To decrease this risk, regularly use a a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10 a.m. - 2 p.m.
- Wear long sleeve shirts, pants, hats, and sunglasses
- Children under 6 month: ask a doctor

##### **Inactive Ingredients**

Bismuth Oxychloride, Iron Oxides, Mica

**Questions or Comments?**  
 Call toll free 1-888-795-4747



## MEDIUM DARK FOUNDATION SPF 15

titanium dioxide, zinc oxide powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:98 132-889
<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	20 g in 100 g

Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)

Titanium Dioxide

7 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:98132-889-08	72 in 1 CASE		
1		8 g in 1 JAR		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/16/2012	

**Labeler** - Bare Escentuals Beauty Inc. (087008363)

**Registrant** - Ei Inc. (105803274)

### Establishment

Name	Address	ID/FEI	Business Operations
Ei Inc.		105803274	manufacture, label, pack

Revised: 6/2012

Bare Escentuals Beauty Inc.