# MEDIUM BEIGE FOUNDATION SPF 15- zinc oxide, titanium dioxide 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.

-----

#### **BareMineral Original SPF 15 Foundation Medium Beige**

**Drug Facts** 

#### **Active Ingredients**

Zinc Oxide 21% Titanium Dioxide 12%

#### **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, Titanium Dioxide, Zinc Oxide

#### **Questions or Comments?**

Call toll free 1-888-795-4747

## Drug Facts (continued)

Inactive ingredients bismuth axychloride, mica, iron axides.

Other information Protect this product from excessive heat and direct sun

Questions or comments? Call toll free 1-888-795-4747

# **Drug Facts**

# Active ingredient(s)

Titanium dioxide 12.6% Zinc coide 21.8% Purpose Sunscreen Sunscreen

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is smallowed, get medical helps or contact a Poison Control Center right away.

Directions For sunscreen use: • apply liberally 15 minutes before sun exposure • use a water resistant 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

#### Drug Facts (continued)

## Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rose with water to remove.

## Drug Facts (continued)

if swimming or sweating - reapply 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

bareMinerals ORIGINAL Foundation Broad Spectrum SPF 15

medium beige

net wt 8 g / 0.28 oz.

98132 26963 1

N20

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 bareMinerals ORIGINAL Foundation **Broad Spectrum SPF 15** 

medium beige N20 net wt 8 g / 0.28 oz.

Dist. by Bare Escentuals Beauty, Inc., San Francisco, CA 94105, USA London WID 30B

bareMinerals ORIGINAL Foundation Broad Spectrum SPF 15

medium beige



ACTIVE INGREDIENTS: Tranium clipxide 12%. Zinc oxide 20%.

See box for complete Drug Facts information

net wt 18 g / 0.6 oz.

Made in USA

MEDIUM BEIGE SPF 15 FOUNDATION: INGREDIENTS: (18 q / 0.5 0z.)

Active Ingredients:

Titanium Dioxide 12.6%

**USES:** Helps prevent sunburn

Purpose

**WARNINGS:** For external use only,

Rinse with water to remove.

**DIRECTIONS:** Apply evenly before sun exposure as needed. Children under 5 months of age:

Other Information: Store at room

**Inactive Ingredients:** Bismuth Exychloride.

#### MEDIUM BEIGE FOUNDATION SPF 15

zinc oxide, titanium dioxide powder

Prod	110t	Info	uma	tion
Proa	116.1		rina	111111

HUMAN OTC DRUG NDC:98132-881 Product Type Item Code (Source)

**Route of Administration TOPICAL** 

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	21 g in 100 g	
Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dio xide	12 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
MICA (UNII: V8A1AW0880)		
BISMUTH O XYCHLO RIDE (UNII: 4ZR792I587)		
BROWN IRON OXIDE (UNII: 1N0 32N7MFO)		
FERRIC OXIDE YELLOW (UNII: EX438 O2MRT)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NI	DC:98132-881-08	72 in 1 CASE		
1		8 g in 1 JAR		
2 NI	DC:98132-881-18	36 in 1 CASE		
2		18 g in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/14/20 12	

# Labeler - Bare Escentuals Beauty Inc. (087008363)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Ei Inc.		105803274	manufacture(98132-881), label(98132-881)	

Revised: 2/2013 Bare Escentuals Beauty Inc.