MEDIUM FOUNDATION SPF 15- 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

Drug Facts

Active Ingredients

Titanium Dioxide 25%

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 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

Questions or Comments?

Drug Facts (continued)

Inactive ingredients bismuth oxychloride, titanium dioxide, mica, iron oxides,

Other information Protect this product from excessive heat and direct sun

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

Drug Facts

Active ingredient(s)

Purpose

Titanium dioxide 25%

Sunscreen

Stop use and ask a 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 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, Rinse with water to remove,

Drug Facts (continued)

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bareMinerals ORIGINAL Foundation Broad Spectrum SPF 15

medium

C25

net wt 8 g / 0.28 oz.



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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 C25

net wt 8 g / 0.28 oz.

Dist. by Bare Escentuals Beauty, Inc., San Francisco, CA 94105, USA London W1D 30B



MEDIUM FOUNDATION SPF 15

titanium dioxide powder

Product Information				
Product Type	oduct Type HUMAN OTC DRUG LABEL Item Code (Source)		NDC:98132-880	
Route of Administration	TOPICAL	DEA Schedule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Titanium Dioxide (Titanium Dioxide)	Titanium Dioxide	25 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
MICA	
BISMUTH O XYCHLO RIDE	
BROWN IRON OXIDE	
FERRIC OXIDE YELLOW	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	NDC:98132-880-08	72 in 1 CASE		
1		8 g in 1 JAR		
2 N	NDC:98132-880-18	64 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 1/16/20 12	
OTC monograph not imai	pattosz	0 1/10/2012	

Labeler - Bare Escentuals Beauty Inc. (087008363)

Registrant - Ei Inc. (105803274)

Establishment			
Name	Address	ID/FEI	Business Operations
Ei Inc.		105803274	manufacture(98132-880), label(98132-880)

Revised: 2/2013 Bare Escentuals Beauty Inc.