

FAIRLY MEDIUM 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.

BareMineral Original SPF 15 Foundation Fairly Medium

Drug Facts

Active Ingredients

Zinc Oxide 9.3%
Titanium Dioxide 25%

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 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
- children under 6 months: ask a doctor
- **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

Inactive Ingredients

Bismuth Oxychloride, Iron Oxides, Mica, Titanium Dioxide

Questions or Comments?

Call toll free 1-888-795-4747

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 toll free 1-888-795-4747

Drug Facts

Active ingredient(s)	Purpose
Titanium dioxide 25%	Sunscreen
Zinc oxide 9.3%	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.

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bareMinerals ORIGINAL Foundation
Broad Spectrum SPF 15

fairly medium C20

net wt 8 g / 0.28 oz.



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Broad Spectrum SPF 15

fairly medium C20

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Dist. by Bare Escentuals Beauty, Inc., San Francisco, CA 94105, USA
London W1D 3DB

FAIRLY MEDIUM FOUNDATION SPF 15

titanium dioxide, zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:98132-924
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	9.3 g in 100 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:98132-924-08	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	11/12/2012	

Labeler - Bare Escentuals Beauty Inc. (087008363)

Registrant - Ei Inc. (105803274)

Establishment

Name	Address	ID/FEI	Business Operations
Ei Inc.		105803274	manufacture(98132-924) , label(98132-924)