

WARM TAN 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 Warm Tan

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

Drug Facts (continued)

Inactive ingredients iron oxides, mica, bismuth oxychloride.

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 7% | Sunscreen |
| Zinc oxide 20% | 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)

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
golden dark **W40**
net wt 8 g / 0.28 oz.



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 ▼



WARM TAN FOUNDATION SPF 15

titanium dioxide, zinc oxide powder

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:98132-884 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---------------------------------------------------------------------------------|-------------------|---------------|
| Zinc Oxide (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) | |
| FERROSO FERRIC 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:98132-884-08 | 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(98132-884) , label(98132-884) , pack(98132-884) |

Revised: 2/2013

Bare Escentuals Beauty Inc.