

LIGHT 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 Light

Drug Facts

Active Ingredients

Zinc Oxide 18%

Titanium Dioxide 16%

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 oxychloride, mica, iron oxides.

Other information Protect this product from excessive heat and direct sun.

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

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

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.

bareMinerals ORIGINAL Foundation
Broad Spectrum SPF 15

light

W15

net wt 8 g / 0.28 oz.



6819

Drug Facts

Active ingredient(s)

Titanium dioxide 18%
Zinc oxide 22%

Purpose

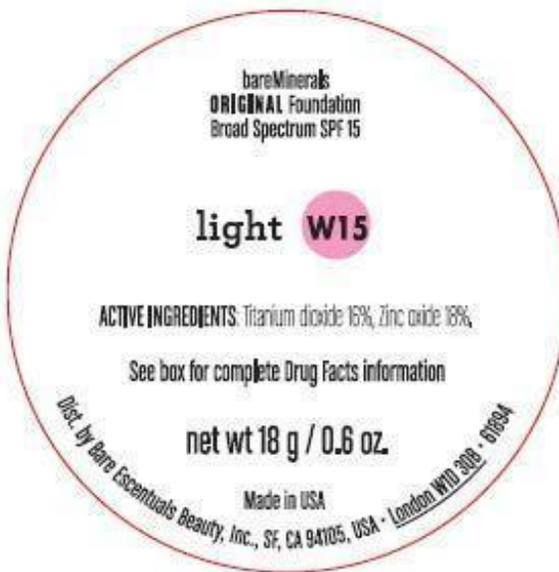
Sunscreen
Sunscreen

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

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

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



LIGHT FOUNDATION SPF 15

titanium dioxide, zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:98132-877
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	18 g in 100 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	16 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:98132-877-08	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
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OTC monograph not final	part352	01/16/2012	
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LIGHT FOUNDATION SPF 15

titanium dioxide, zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:98132-873
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	18 g in 100 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	16 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:98132-873-18	36 in 1 CASE		
1		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	10/02/2010	

Labeler - Bare Escentuals Beauty Inc. (087008363)

Registrant - Ei Inc. (105803274)

Establishment

Name	Address	ID/FEI	Business Operations
Ei Inc.		105803274	manufacture(98132-877) , label(98132-877)