DARK FOUNDATION SPF 15- titanium dioxide, zinc oxide powder
Ei 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 Dark

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

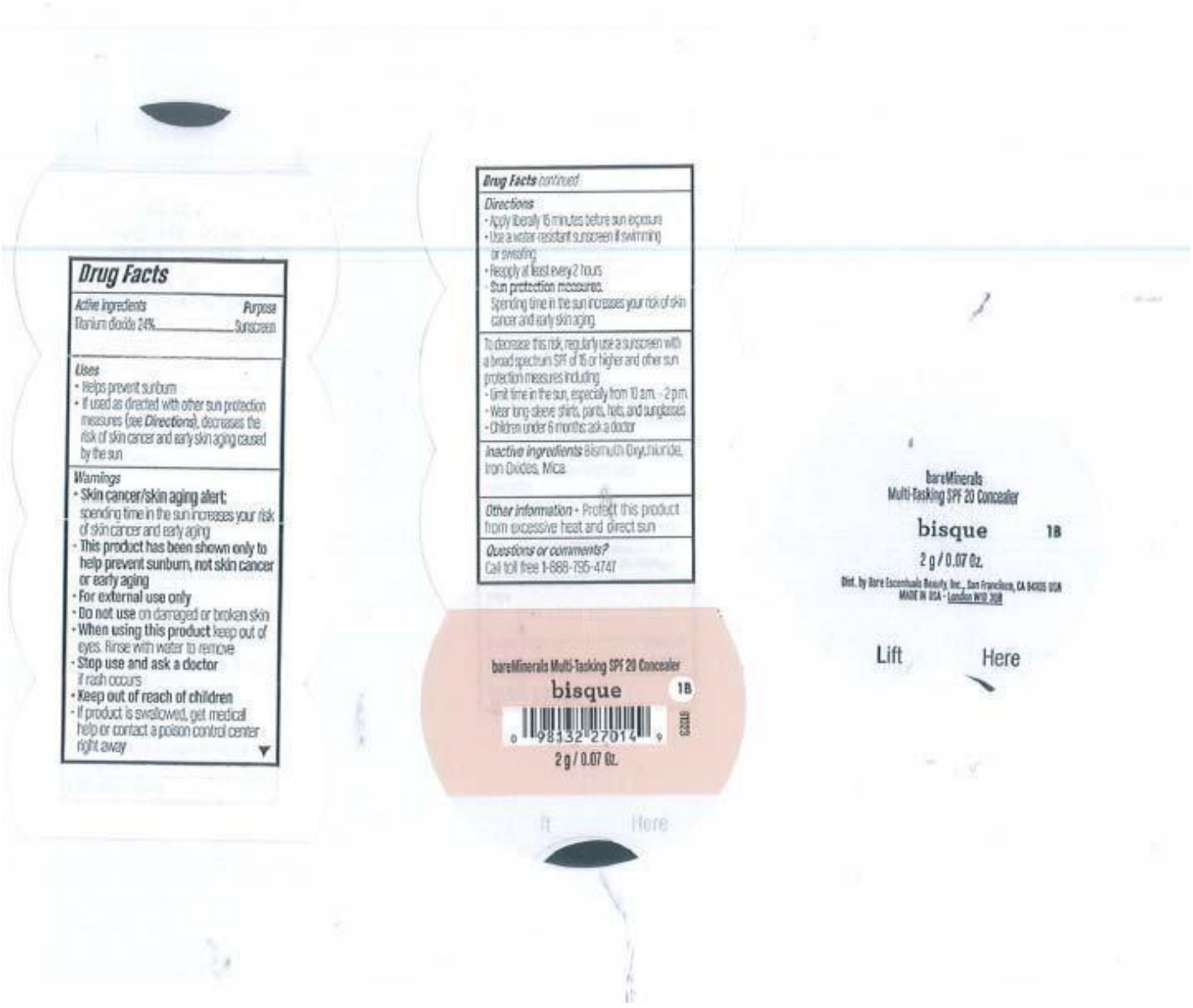
- Apply liberally 15 minutes before sun exposure
- Use a water-resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- **Sun protection measures.** Spending time in the sun increases your risk of skin cancer or early skin aging. To decrease this risk, regularly use a a sunscreen 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, Titanium Dioxide

Questions or Comments?

Call toll free 1-888-795-4747



DARK FOUNDATION SPF 15

titanium dioxide, zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52512-501
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)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52512-501-08	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	05/16/2012	

Labeler - Ei Inc. (105803274)

Establishment

Name	Address	ID/FEI	Business Operations
Ei Inc.		105803274	manufacture(52512-501) , label(52512-501) , pack(52512-501)

Revised: 4/2013 Ei Inc.