

WARM DARK ORIGINAL- titanium dioxide and 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.

Warm Dark Original

Drug Facts

Active Ingredients

Titanium Dioxide 7%
Zinc oxide 20

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

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

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If 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 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 10am to 2 pm, wear long-sleeve shirts, pants, hats, and sunglasses.

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

Bare Escentuals

MADE IN USA

Distr. By Bare Escentuals Beauty Inc., San Francisco CA 94104 USA

London W10 3QB

PRINCIPAL DISPLAY PANEL - 8 g Jar Label

bareMinerals **ORIGINAL** Foundation

Broad Spectrum SPF 15

warm dark

W45

net wt 8 g / 0.28 oz.

Drug Facts (continued)

Warnings

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bareMinerals ORIGINAL Foundation
Broad Spectrum SPF 15

warm dark **W45**

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London WTD 308

Drug Facts (continued)

Inactive ingredients iron oxides, bismuth oxychloride, mica.

Other information Protect this product from excessive heat and direct sun

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Active ingredient(s)

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Sunscreen

Sunscreen

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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)

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

WARM DARK ORIGINAL
titanium dioxide and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:98 132-148
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	7 g in 100 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Bismuth Oxychloride (UNII: 4ZR792I587)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Mica (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:98 132-148-01	0.75 g in 1 JAR		
2	NDC:98 132-148-02	2 g in 1 JAR		
3	NDC:98 132-148-03	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	01/05/2010	

Labeler - Bare Escentuals Beauty Inc. (087008363)

