CREAM- titanium dioxide cream Oxygen Development LLC

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.

Bare Minerals 5 in 1 BB advanced performance cream eyeshadow broad spectrum spf 15 - Exotic Lilac

Active Ingredient

Titanium Dioxide 17%. Purpose: Sunscreen

Purpose

Sunscreen

Uses

helps prevent sunburn if used as directed with other sun protection measures. Decreased 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 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 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 the 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 2pm
- wear long-slevve shirts, pants, hats, and sunglasses

Inactive ingredients

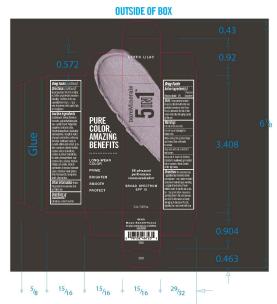
isododecane, disteardimonium hectorite, Polymethylsilsesquioxane, Caprylic/Capric Triglyceride, propylene carbonate, silica, Trimethylsiloxysilicate, Dipalmitoyl Hydroxyproline, Mangifera Indica (Mango) Seed Butter, Carthamus Tinctorius (Safflower) Seed Oil, Camellia Oleifera Leaf Extract, Acrylates Copolymer, Diacetyl Boldine, Calcium Sodium Borosilicate, Calcium Aluminum Borosilicate, tin oxide, phenoxyethanol, may contain: mica, carmine, titanium dioxide, iron oxides, Bismuth Oxychloride,chromium hydroxide green, chromium oxide greens, ferric fenocyanide, manganese violet, ultramarines

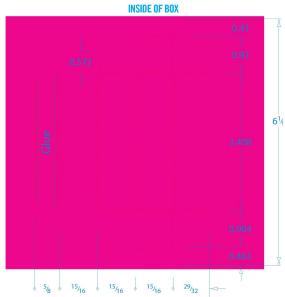
other information

protect this product from excessive heat and direct sun

package label







CREAM

titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	17 mg in 100 mg	

Inactive Ingredients		
Ingredient Name	Strength	
TRIMETHYLSILOXYSILICATE (M/Q 0.66) (UNII: 5041RX63GN)		
MANGO SEED OIL (UNII: K8LOR30915)		
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)		
ISODODECANE (UNII: A8289P68Y2)		
MICA (UNII: V8A1AW0880)		
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)		
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)		
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)		

PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-080- 12	1 in 1 CARTON	02/22/2021	02/10/2023
1	NDC:61354-080- 06	3 mg in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/22/2021	

Labeler - Oxygen Development LLC (137098492)

Establishment				
Name	Address	ID/FEI	Business Operations	
Oxygen Development LLC		137098492	manufacture(61354-080)	

Revised: 2/2023 Oxygen Development LLC