LONG WEAR GET OVER BB- titanium dioxide, zinc oxide cream 1004LABORATORY

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.

ACTIVE INGREDIENT

Active Ingredient: Titanium Dioxide 11.25%, Zinc Oxide 4.90%

INACTIVE INGREDIENT

Inactive Ingredients: Glycyrrhiza Glabra (Licorice) Root Water, Camellia Sinensis Leaf Water, Aloe Barbadensis Leaf Water, Coco-Caprylate/Caprate, Dicaprylyl Carbonate, Polyglyceryl-3 Diisostearate, Glycerin, Isoamyl Laurate, Polyglyceryl-2 Dipolyhydroxyste arate, Sodium Chloride, Calen dula Officinalis Flower Extract, Sorbitan Olivate, NelumboNu cifera Flower Water, Centaurea Cyanus Flower Water, Lacto bacillus/Hibiscus Sabdariffa Flower Ferment Filtrate, Rosa Centifolia Flower Water, Zant hoxylum Piperitum Fruit Ext ract, Pulsatilla Koreana Extract, Usnea Barbata (Lichen) Extract, Cocos Nucifera (Coco nut) Oil, Hippophae Rham no ides Seed Oil, Voacanga Afri cana Seed Extract, Rosa Cani na Fruit Extract, Yellow Oxide of Iron, alpha-bisabolol, Water, Morus Alba Bark Extract, Saccharomyces/Caragana Sinica Root Ferment Extract, Glycine Max (Soybean) Seed Extract, Chamomilla Recutita (Ma tricaria) Flower/Leaf Extract, Rosmarinus Officinalis (Rosemary) Extract, Lavandula Angustifolia (Lavender) Extract, Monarda Didyma Leaf Extract, Ocimum Basilicum (Basil) Leaf Extract, Salvia Officinalis (Sage) Leaf Extract, Origanum Vulg are Leaf Extract, Mentha Viri dis (Spearmint) Extract, Melissa Officinalis Extract, Ethyl Ferulate, Oenothera Biennis (Evening Primrose) Oil, Borago Officinalis Seed Oil, Pistacia Vera Seed Oil, Red Oxide of Iron, Glyceryl Caprylate, Aluminum Hydroxide, stearic Acid, Citrus Aurantium Dulcis (Orange) Oil, Glycyrrhiza Glabra (Licorice) Root Extract, Rhodiola Rosea Root Extract, Rosa Damascena Flower Extract, Taraxacum Offi cinale (Dandelion) Leaf Extract, Olea Europaea (Olive) Leaf Extract, Mangifera Indica (Mango) Seed Butter, Argania Spinosa Kernel Oil, Black Oxide of Iron, Lavandula Angustifolia(Lavender) Oil, Adenosine

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings: 1. Stop using the product if the following problems arise while using the product as continued use could worsen the symptoms; consult with a dermatologist. A. If red spots, swelling, itchiness, and irritation occur. B. If the above problems occur on the applied area on the skin from direct sunlight 2. Do not use on areas with wounds, eczema, and dermatitis. 3. Storage and handling precautions A. Close the lid after use. B. Keep away from the reach of babies and children. C. Do not store in high-temperature or low-temperature and keep away from direct sunlight 4. Wash off the product if it gets in the eye

DESCRIPTION

Indications & Usage: After washing the face, dispense an appropriate amount into your palm, and evenly apply to the entire face.

Dosage & Administration: Use the eyedropper to pump 1~2times.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



LONG WEAR GET OVER BB

titanium dioxide, zinc oxide cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69739-020	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	Titanium Dioxide	3.37 mg in 30 mL
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.47 mg in 30 mL

Inactive Ingredients	
Ingredient Name	Strength
Licorice (UNII: 61ZBX54883)	

l	Pac	ckaging			
l	# Item Code Package Description		Marketing Start Date	Marketing End Date	
l	1 N	DC:69739-020-01	30 mL in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	03/01/2015		

Labeler - 1004LABORATORY (689512629)

Registrant - 1004LABORATORY (689512629)

Establishment				
Name	Address	ID/FEI	Business Operations	
1004LABORATORY		689512629	manufacture(69739-020)	

Revised: 4/2015 1004LABORATORY