

TONYMOLY LUMINOUS GODDESS AURA BB 02- titanium dioxide, octinoxate, zinc oxide cream

Tonymoly Co., Ltd.

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 Ingredients: Titanium Dioxide 9.94%, Ethylhexyl Methoxycinnamate 7.00%, Zinc Oxide 2.94%

INACTIVE INGREDIENT

Inactive Ingredients: Water, Cyclopentasiloxane, Dipropylene Glycol, Butylene Glycol, Dicaprylate/Dicaprate, Phenyl Trimethicone, Cyclohexasiloxane, Cetyl PEG/PPG-10/1 Dimethicone, Arbutin, Hexyldecyl Myristoyl Methylaminopropionate, Hexyl Laurate, Iron Oxides (CI 77492), Sorbitan Sesquioleate, Magnesium Sulfate, Phenoxyethanol, Distearidimonium Hectorite, Isoamyl p-Methoxycinnamate, Silica, Iron Oxides (CI 77491), Tribehenin, Iron Oxides (CI 77499), Aluminum Hydroxide, C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Stearic Acid, Triethoxycaprylylsilane, Glyceryl Behenate, Calcium Stearate, Polyglyceryl-6 Octastearate, Fragrance(Parfum), Ethylhexylglycerin, Dimethicone, Disodium EDTA, Adenosine, Water, Butylene Glycol, Ceramide 3, Tremella Fuciformis (Mushroom) Extract, Mica (CI 77019), Glycerin, Melissa Officinalis Leaf Extract, Malva Sylvestris (Mallow) Extract, Achillea Millefolium Extract, Alchemilla Vulgaris Extract, Primula Veris Extract, Mentha Piperita (Peppermint) Leaf Extract, Veronica Officinalis Extract, Ethyl Hexanediol, Oxygen

PURPOSE

Purpose: Sunscreen

WARNINGS

Warning: 1. In case of having following symptoms after using this, you're advised to stop using it immediately. If you keep using it, the symptoms will get worse and need to consult a dermatologist. 1) In case of having problems such as red rash, swollenness, itching, stimulation during usage. 2) In case of having the same symptoms above on the part you put this product on by direct sunlight. 2. You are banned to use it on the part where you have a scar, eczema, or dermatitis. 3. In case of getting it into your eyes, you have to wash it immediately.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of Children: Keep out of reach of babies and children

INDICATIONS & USAGE

Indication & Usage: After application of skin care products, apply on face using fingertips or sponge.

DOSAGE & ADMINISTRATION

Dosage & Administration: Take an adequate amount of this product.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Image of carton



TONYMOLY LUMINOUS GODDESS AURA BB 02

titanium dioxide, octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59078-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	4.47 g in 45 g
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	3.15 g in 45 g
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.32 g in 45 g

Inactive Ingredients

Ingredient Name	Strength

Water (UNII: 059QF0K00R)				
Dipropylene Glycol (UNII: E107L85C40)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59078-052-01	45 g in 1 CARTON		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	05/01/2014		

Labeler - Tonymoly Co., Ltd. (688216798)

Registrant - Tonymoly Co., Ltd. (688216798)

Establishment			
Name	Address	ID/FEI	Business Operations
Tonymoly Co., Ltd.		688216798	repack(59078-052)

Establishment			
Name	Address	ID/FEI	Business Operations
COSMAX INC.		689019313	manufacture(59078-052)