DR YOUNG PROTECT PREVENT TRIPLE ACTION BB- titanium dioxide, octinoxate cream Tdc, 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 8.0%, Ethylhexyl Methoxycinnamate 7.5%

INACTIVE INGREDIENT

Inactive ingredients: Water, Phenyl Trimethicone, Propylene Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Arbutin, Cyclopentasiloxane, Hexyl Laurate, Cyclohexasiloxane, Methyl Methacrylate Crosspolymer, Iron Oxides (CI 77492), Glycerin, Magnesium Sulfate, Sorbitan Sesquioleate, Zinc stearate, Caprylyl Methicone, Dimethicone, Microcrystalline Wax, Ozokerite, Isostearyl Isostearate, Polyglyceryl-4 Isostearate, Iron Oxides (CI 77491), Iron Oxides (CI 77499), Quaternium-18 Bentonite, Dimethicone/Vinyl Dimethicone Crosspolymer, Phenoxyethanol, Triethoxycaprylylsilane, Sodium Chloride, Silica Dimethyl Silylate, PEG/PPG-19/19 Dimethicone, Phellinus Linteus Extract, Cyclotetrasiloxane, Caprylyl Glycol, Butylene Glycol, Portulaca Oleracea Extract, Allantoin, Hydroxyethylcellulose, Ultramarines(CI 77007), Centella Asiatica Extract, Piper Methysticum Leaf/Root/Stem Extract, Adenosine, Caprylhydroxamic Acid, Petrolatum, Tocopheryl Acetate, Mica, Polysilicone-11, Aloe Barbadensis Leaf Juice, Lilium Candidum Bulb Extract, Iris Versicolor Extract, Freesia Alba Flower Extract, Narcissus Pseudo-Narcissus (Daffodil) Flower Extract, Rosa Damascena Flower Water, Leontopodium Alpinum Extract, Nelumbo Nucifera Flower Extract, Jasminum Officinale (Jasmine) Flower/Leaf Extract

PURPOSE

Purpose: Sunscreen

WARNINGS

Warning: 1) For external use only. 2) Consult a dermatologist if the first sign occurs like red spot, swelling, itching, or any allergic reactions. 3) Avoid direct contact with eyes. 4) If contact occurs, flush thoroughly with water. 5) If swallowed, get medical help or contact a Poison Control Center right away. 6) Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

Storage and cautions for handling: 1) Keep out of reach of children. 2) Keep away from high or low temperature and direct sunlight.

DESCRIPTION

Uses: - Ultralight, Multifunctional beauty cream to protect, perfect, tint, and moisturize skin - Features SPF 33 PA+++ sun protection

Directions: Apply moderate amount on entire face after basic skin care.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Triple Action BB [Protect Prevent]

Uses

Ultralight, Multifunctional beauty cream to protect, perfect, tint, and moisturize skin Features SPF 33 PA+++ sun protection

PURPOSE

Sunscreen

Directions

Apply moderate amount on entire face after basic skin care.

Warnings

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Storage and cautions for handling: 1) Keep out of reach of children. 2) Keep away from high or low temperature and direct sunlight.

Manufactured for TDC Co., Ltd. 91 Baekjegobun-ro, Songpa-gu, Seoul, 05562, Korea

Manufactured by Biocostec Co., Ltd. 53, Dodam 5-ro, Seo-gu, Incheon, Korea Tel: +82-32-822-0244 Fax: +82-32-822-0334

Questions

ACTIVE INGREDIENTS

Titanium Dioxide 8.0% Ethylhexyl Methoxycinnamate 7.5%

INACTIVE INGREDIENTS

Water, Phenyl Trimethicone, Propylene Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Arbutin, Cyclopentasiloxane, Hexyl Laurate, Cyclohexasiloxane, Methyl Methacrylate Crosspolymer, Iron Oxides (Cl 77492), Glycerin, Magnesium Sulfate, Sorbitan Sesquioleate, Zinc stearate, Caprylyl Methicone, Dimethicone, Microcrystalline Wax, Ozokerite, Isostearyl Isostearate, Polyglyceryl-4 Isostearate, Iron Oxides (Cl. 77491), Iron Oxides (Cl 77499), Quaternium-18 Bentonite, Dimethicone/Vinyl Dimethicone Crosspolymer, Phenoxyethanol, Triethoxycaprylylsilane, Sodium Chloride, Silica Dimethyl Silylate, PEG/PPG-19/19 Dimethicone, Phellinus Linteus Extract, Cyclotetrasiloxane, Caprylyl Glycol, Butylene Glycol, Portulaca Oleracea Extract, Allantoin, Hydroxyethylcellulose, Ultramarines(Cl 77007), Centella Asiatica Extract, Piper Methysticum Leaf/Root/Stem Extract, Adenosine, Caprylhydroxamic Acid, Petrolatum, Tocopheryl Acetate, Mica, Polysilicone-11, Aloe Barbadensis Leaf Juice, Lilium Candidum Bulb Extract, Iris Versicolor Extract, Freesia Alba Flower Extract, Narcissus Pseudo-Narcissus (Daffodil) Flower Extract, Rosa Damascena Flower Water, Leontopodium Alpinum Extract, Nelumbo

www.dr-young.co.kr

30 ml



DR YOUNG PROTECT PREVENT TRIPLE ACTION BB

titanium dioxide, octinoxate cream

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:43948-13
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Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Titanium Dioxide (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP) Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) Octinoxate 2.25 g in 30 mL

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Phenyl Trimethicone (UNII: DR0K5NOJ4R)			

l	Packaging						
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
l	1 NDC:43948-1330-2	1 in 1 CARTON	10/01/2017				
	1 NDC:43948-1330-1	30 mL in 1 TUBE; 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	10/01/2017					

Labeler - Tdc, Co. Ltd (687479378)

Registrant - Tdc, Co. Ltd (687479378)

Establishment						
Name	Address	ID/FEI	Business Operations			
NEW & NEW CO.,LTD.		557821160	manufacture(43948-1330)			

Revised: 11/2017 Tdc, Co. Ltd