

PLUSTEM UV PERFECT BLOCK ESSENCE- octinoxate, titanium dioxide cream ONA

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: ETHYLHEXYL METHOXYCINNAMATE 7.2%, TITANIUM DIOXIDE 4.4%

INACTIVE INGREDIENT

Inactive Ingredients: WATER, BUTYLENE GLYCOL, CYCLOPENTASILOXANE, DICAPRYLYL CARBONATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, DIMETHICONE, BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENYL TRIAZINE, ISOAMYL P-METHOXYCINNAMATE, ISOHEXADECANE, CETYL PEG/PPG-10/1 DIMETHICONE, NIACINAMIDE, SODIUM CHLORIDE, SILICA, ISOSTEARIC ACID, HYDROLYZED COLLAGEN, ADENOSINE, CAMELLIA SINENSIS CALLUS CULTURE EXTRACT, NELUMBO NUCIFERA FLOWER EXTRACT, LONICERA JAPONICA (HONEYSUCKLE) FLOWER EXTRACT, SOPHORA JAPONICA FLOWER EXTRACT, CARTHAMUS TINCTORIUS (SAFFLOWER) FLOWER EXTRACT, PYRUS COMMUNIS (PEAR) FLOWER EXTRACT, PRUNUS MUME FLOWER EXTRACT, CAMELLIA JAPONICA FLOWER EXTRACT, ZIZYPHUS JUJUBA SEED EXTRACT, SCROPHULARIA BUERGERIANA ROOT EXTRACT, OPHIOPOGON JAPONICUS ROOT EXTRACT, SCHIZANDRA CHINENSIS FRUIT EXTRACT, PANAX GINSENG ROOT EXTRACT, ANGELICA GIGAS ROOT EXTRACT, PORIA COCOS EXTRACT, ACORUS GRAMINEUS ROOT/STEM EXTRACT, ASPARAGUS COCHINCHINENSIS ROOT EXTRACT, REHMANNIA GLUTINOSA ROOT EXTRACT, PLATYCODON GRANDIFLORUM ROOT EXTRACT, CERAMIDE 3, HYDROGENATED LECITHIN, SALVIA MILTIORRHIZA FLOWER/LEAF/ROOT EXTRACT, COPTIS CHINENSIS ROOT EXTRACT, THUJA ORIENTALIS SEED EXTRACT, POLYGALA TENUIFOLIA ROOT EXTRACT, PORTULACA OLERACEA EXTRACT, SODIUM HYALURONATE, DIMETHICONE CROSSPOLYMER, GLYCERYL BEHENATE/EICOSADIOATE, XYLITOL, STEARALKONIUM HECTORITE, DEXTRIN PALMITATE, ALUMINUM HYDROXIDE, CAPRYLYL GLYCOL, POLYGLYCERYL-6 POLYRICINOLEATE, STEARIC ACID, PROPYLENE CARBONATE, CELLULOSE GUM, GLYCERIN, ZINC OXIDE, 1,2-HEXANEDIOL, ETHYLHEXYLGLYCERIN, FRAGRANCE, PHENOXYETHANOL, DISODIUM EDTA, ETHYLHEXYLGLYCERIN, IRON OXIDES(CI77492), IRON OXIDES(CI77491)

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings: 1. Please stop using the product if the following abnormal conditions exist after the application of the product. If you continue to use, it may worsen the symptom. Please consult with dermatologist. 1) When any abnormal condition exists during its use such as red spot, swelling, itching, or irritation 2) When any abnormal condition as above examples in 1) exists on the applied part by a direct sunlight 2. Please do not use the product on abnormal parts such as injured part, eczema and dermatitis. 3. Precautions for Storage and Handling a. Please make sure to close the cover after its use. b. Please keep the product out of reach by the hands of infant and children. c. Please do not store the

product in the place of high or low temperature, and of direct sunlight. 4. UV protection index and UV A protection level of the present product have been measured by the standard of UV Protection Effect and Measurement Method notified by The Ministry of Foods & Drug Safety. 5. Please do not drink as the present product is cosmetics. If you drink it, please throw it up. If any abnormality exists, please consult with a doctor. Please do not put other contents in the container to use. 6. When the product stains on clothing, please do not wash it with water but with dry cleaning.

DESCRIPTION

Use: In the last stage of basic touch, spread the product on face and parts (arms and legs, etc) which are easily exposed to the sun light. After drying sweat and water with towels, apply the product again as the effect of UV protection declines.

Directions: Triple Functional Cosmetics with Whitening, Wrinkle Improvement and UV Protection Protect skin from UV (SPF50+,PA+++). It helps improve skin wrinkles. It helps lighten skin. Take proper amount of the present product and spread evenly on the skin Sun Block Lotion that creates a moisturizing natural skin tone - This lotion protects skin effectively by blocking UVA and UVB at the same time. - Components of Hyaluronic Acid and Ceramide with excellent skin moisturizing effect prevent skin from the evaporation of moisture by UV and solar heat and maintain moisturizing skin. - This lotion corrects skin tone naturally to create uniform and smooth skin tone.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71060-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.6 g in 50 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.2 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71060-020-02	1 in 1 CARTON	10/10/2016	
1	NDC:71060-020-01	50 g 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	10/10/2016	

Labeler - ONA (689851847)**Registrant** - ONA (689851847)**Establishment**

Name	Address	ID/FEI	Business Operations
ONA		689851847	manufacture(71060-020)