PHOTOBLOCK PLUS- avobenzone, titanium dioxide, bis-ethylhexyl hydroxydimethoxy benzylmalonate cream Pella Pharmaceuticals 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.

Photoblock Plus

Forms and Presentation

Cream: Tube of 75 g.

Active Ingredients

Avobenzone

Titanium Dioxide

Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate

Inactive Ingredients

Aqua, Glycerin, Isopropyl Myristate, Cetearyl Alcohol, Ceteareth-22, Glyceryl Stearate, Disodium Phosphate, Citric Acid, Methylparaben, Propylparaben and BHA.

Purpose

Sunscreen

Properties

Photoblock [®] Plus Cream is a sunscreen and anti-aging cream. which is characterized by its maximum protection SPF 50 + (recognized by global health authorities and scientists) that protects against UVA and UVB.

Photoblock $^{\circledR}$ Plus Cream does not cause acne and will not clog pores. Photoblock $^{\circledR}$ Plus Cream provides sustained protection during peak daytime temperature.

Indications

Photoblock [®] Plus Cream is used to provide maximum sun protection while maintaining a youthful and radiant skin.

Photoblock [®] Plus Cream protects the skin against premature aging caused by exposure to UVA due to its components Ronacare AP and Parsol 1789 (A vobenzone), the only substances approved by the American FDA "Food and Drug Administration", which provide complete protection against UVA. It also contains Titanium Dioxide which

provides protection against UVB rays that cause redness and burns.

Contraindications

Hypersensitivity to any of the components.

Precautions

• Keep out of reach of children

Warnings

- For external use only
- Avoid conact with eyes

Side effects

Photoblock ® Plus Cream has no known side effects, its use is harmless.

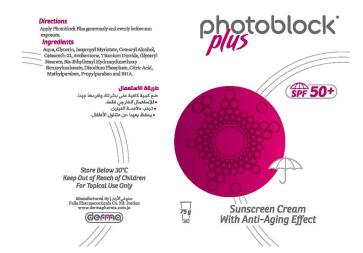
Dosage and administration

Apply Photoblock [®] Plus Cream about 15 minutes before sun exposure. Apply Photoblock [®] Plus Cream on intact skin, apply a sufficient amount and massage gently. Reapply every 2 hours or after swimming or sports.

Storage conditions

Store at a temperature below 30 $^{\circ}$ C.

Primary Package



Secondary Package



PHOTOBLOCK PLUS

avobenzone, titanium dioxide, bis-ethylhexyl hydroxydimethoxy benzylmalonate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82160-276	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	22.5 mg in 75 g		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	22.5 mg in 75 g		
BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYLMALONATE (UNII: 7D4Q5YJ8NV) (BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYLMALONATE - UNII: 7D4Q5YJ8NV)	BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYLMALONATE	7.5 mg in 75 g		

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
CETEARETH-22 (UNII: 28VZG1E234)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)		
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:82160-276- 01	1 in 1 CARTON	03/15/2011		
1		75 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	03/15/2011		

Labeler - Pella Pharmaceuticals Co. Ltd (562370925)

Revised: 11/2021 Pella Pharmaceuticals Co. Ltd