

**PHOTOBLOCK- avobenzone, bis-ethylhexyl hydroxydimethoxy
benzylmalonate gel
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.

Photo Gel

Forms and Presentation

Gel: Tube of 75 g.

Active ingredients

Avobenzone

Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate

Inactive Ingredients

Aqua, Alcohol, Glycerin, Isopropyl Myristate, Cetareth-25, Carbomer, Methylparaben, Triethanolamine, Propylparaben and Disodium EDT A.

Purpose

Sunscreen

Properties

Photoblock ® Gel is a gel sunscreen with a protection factor SPF 50. The Photoblock ® Gel sunscreen is distinguished by its special formula; it is suitable for oily and acne-prone skin, Photoblock ® Gel provides long-term protection during times of peak temperatures during the day.

Indications

Photoblock ® Gel with its protection SPF 50 is recommended for oily and acne-prone skin.

Precautions

Keep out of reach of children

Warnings

- For external use only
- Avoid contact with eyes

Contraindications

Hypersensitivity to any of the components.

Side effects

Photoblock[®] Gel has no known side effects, its use is harmless.

Dosage and administration

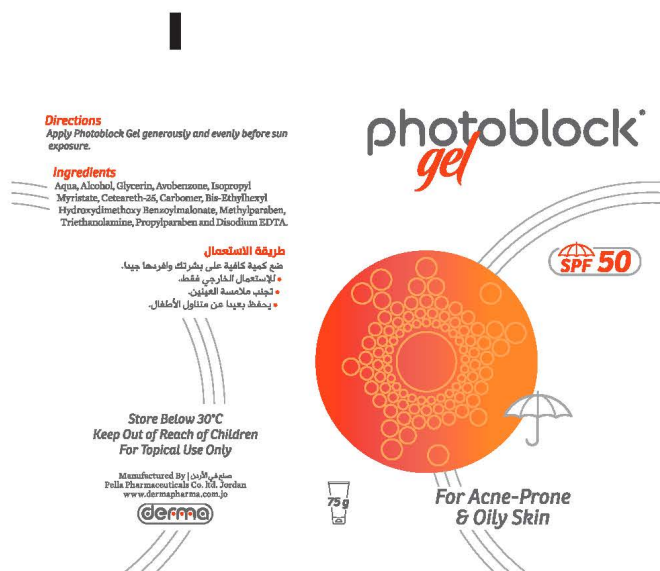
Apply Photoblock[®] Gel before sun exposure and on dry skin, apply a sufficient amount of Photoblock[®] Gel and spread it well on the whole area.

Reapply every 2 hours or after swimming or sports.

Storage conditions

Store at a temperature below 30 ° C.

Primary Package



Secondary Package



PHOTOBLOCK

avobenzone, bis-ethylhexyl hydroxydimethoxy benzylmalonate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82160-344
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYLALONATE (UNII: 7D4Q5YJ8NV) (BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYLALONATE - UNII:7D4Q5YJ8NV)	BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYLALONATE	3.75 mg in 75 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 75 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CETEARETH-25 (UNII: 8FA93U5T67)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82160-344-01	1 in 1 CARTON	07/07/2011	
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	07/07/2011	

Labeler - Pella Pharmaceuticals Co. Ltd (562370925)

Revised: 11/2021

Pella Pharmaceuticals Co. Ltd