

DERMA PELLA SUNSCREEN ADVANCE CREAM-GEL- octocrylene, avobenzone, ethylhexyl salicylate, phenylbenzimidazole sulfonic acid, polysilicone-15, titanium dioxide 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.

Sunscreen Advance

Form and Presentation

Cream-Gel: Plastic Tube, 50 g

Active Ingredients

Octocrylene, Butyl Methoxydibenzoylmethane (Avobenzone), Ethylhexyl Salicylate, Phenylbenzimidazole Sulfonic Acid, Polysilicone-15, Titanium Dioxide

Inactive Ingredients

Aqua, Butylene Glycol Dicaprylate/Dicaprate, Potassium Cetyl Phosphate, Silica, Diisopropyl Sebacate, Butylene Glycol, C12-15 Alkyl Benzoate, Cetearyl Alcohol, Behenyl Alcohol, Tromethamine, VP/Hexadecene Copolymer, Phenoxyethanol, Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate, Xanthan Gum, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA, Ethylhexylglycerin

Purpose

Sunscreen

Properties

This product is developed to be suitable for all types of skin, with high sun protection factors (SPF 50 +) and optimum combination of UVB/UVA filters, they efficiently protect the skin pigmentation spots and skin ageing.

It is fast absorbing with dry touch and matte feel for optimal protection without leaving any white residue on skin.

Paraben Free, Water resistant.

Indications

Sunscreen for all skin types

Precautions

Keep out of reach of children

Warnings

- If irritation occurs, immediately rinse with water and discontinue use.
- If irritation persists, consult with a physician.
- Keep away from your eyes, in case of eye contact, flush with water.
- For external use only.

Contraindications

Hypersensitivity to any of the components.

Side Effects

There are no known side effects.

Dosage and Administration

Apply a sufficient amount of the sunscreen about 15 minutes before sun exposure on intact skin and massage gently. Reapply every 2 hours, after swimming, or sport.

Storage Conditions

Store below 30 °C.

Primary Package



Secondary Package



DERMA PELLA SUNSCREEN ADVANCE CREAM-GEL

octocrylene, avobenzone, ethylhexyl salicylate, phenylbenzimidazole sulfonic acid, polysilicone-15, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82160-726
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	20 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	16 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
POLYSILICONE-15 (UNII: F8DRP5BB29) (POLYSILICONE-15 - UNII:F8DRP5BB29)	POLYSILICONE-15	20 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
DOCOSANOL (UNII: 9G1OE216XY)	
HEXADECYL POVIDONE (UNII: AG75W62QYU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYL MALONATE (UNII: 7D4Q5YJ8NV)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: 75D21FL1PI)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82160-726-01	1 in 1 CARTON	12/26/2022	
1		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 final	M020	12/26/2022	

Labeler - Pella Pharmaceuticals Co. Ltd (562370925)