

**DERMA PELLA SUNSCREEN ADVANCE CREAM-GEL- octocrylene, avobenzone, ethylhexyl salicylate, phenylbenzimidazole sulfonic acid, polysilicone-15, titanium dioxide cream**  
**Pella Pharmaceuticals Co. Ltd**

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**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

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

## Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 809Y72KV36)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>HEXADECYL POVIDONE</b> (UNII: AG75W62QYU)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TROMETHAMINE</b> (UNII: 023C2WHX2V)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYL MALONATE</b> (UNII: 7D4Q5YJ8NV)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: 75D21FL1PI)	

### 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 Drug	M020	12/26/2022	

**Labeler** - Pella Pharmaceuticals Co. Ltd (562370925)