DERMA LIGHTENING- hydroquinone, tretinoin cream
Pella Pharmaceuticals Co. Ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Lightening

Forms and Presentation

Cream: Tube of 30 g.

Active Ingredients

Hydroquinone 2%

Tretinoin 0.025%

Inactive Ingredients

Aqua, Glycerin, Cetyl Alcohol, Ceteareth- 25, Cetearyl Alcohol, Caprylic / Capric Triglyceride, Dimethicone, Stearic Acid, Petrolatum, Benzyl Alcohol, Sodium Lauryl Sulphate, Potassium Sorbate, Sodium Metabisulfite, Parfum and BHA

Purpose

Lightening Cream

Properties

Night cream that lightens and moisturizes the skin.
Paraben free.

Indications

Whitening of skin.
Reduction of spots due to sunlight exposure.
Pregnancy Mask (Melasma). (Use after pregnancy)
Reduction of secular pigmentations of acne.
Can be used on knees and elbows.

Precaution

keep out of reach of children

Warnings

- For external use only
- Avoid contact with eyes
- Do not expose to sunlight and wear protective clothing

Contraindications

Hypersensitivity to any of the components.

Side effects

There are no known side effects.

Dosage and administration

Apply the cream once daily at night after cleansing. Then rub it gently.

Storage conditions

Store at a temperature be]ow 30 °C.
Do not store after a month from opening the tube.

Primary Package

Secondary Package

DERMA LIGHTENING

hydroquinone, tretinoin cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82160-412
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	6 mg in 30 g
TRETINOIN (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R)	TRETINOIN	0.075 mg in 30 g

Inactive Ingredients	
Ingredient Name	**Strength**

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
DIMETHICONE 100 (UNII: RO266O364U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETEARETH-25 (UNII: 8FA93U5T67)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82160-412-01	1 in 1 CARTON	12/24/2014	
1		30 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
unapproved drug other		12/24/2014	

Labeler - Pella Pharmaceuticals Co. Ltd (562370925)

Revised: 12/2021 Pella Pharmaceuticals Co. Ltd