ACTIVE 4- hydroquinone cream
Vivier Pharma, Inc.

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.

Active 4

Active Ingredient

Hydroquinone USP (4%)

Indication

Skin Lightening

Indication

To gradually lighten hyperpigmentation of the skin such as age spots, liver spots, freckles or hyperpigmentation that can occur as a result of pregnancy or the use of oral contraceptives.

Precautions

For external use only. Use only on the advice of a physician. A mild transient stinging may occur for people with sensitive skin. Do not use on broken or irritated skin. Discontinue use if irritation or rash occurs. Avoid contact with eyes and mucous membranes. In case of contact, rinse thoroughly with water. Do not use on children under 12 years of age. Keep out of reach of children. Avoid usage around the eyes and lips.

Precautions

Keep out of reach of children.

Directions

Use fingertips to apply a thin layer to affected areas. Use both morning and night or as directed by a physician. Gradual lightening of the discolored area can be expected in most cases. Close cap securely after each use. Store at room temperature (15-30°C / 59-86°F).

Non-Medicinal Ingredients

Butylated Hydroxy Toluene, Cetearyl Alcohol, Cetyl Alcohol, Disodium EDTA, Ethoxydiglycol, Fragrance/Parfum, Glycerin, Lactic Acid, L-Ascorbic Acid USP, Methylparaben, Phenyl Trimethicone, PPG-2 Myristyl Ether Propionate, Propylparaben, Sodium Cetearyl Sulfate, Sodium Lauryl Sulfate, Sodium Metabisulfite, Tocopheryl Acetate, Triethanolamine Salicylate, Water/Eau.

Principal Display Panel

ACTIVE 4

hydroquinone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67226-2140
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	4 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	

ASCORBIC ACID (UNII: PQ6CK8PD0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67226-2140-6	1 in 1 BOX		
1		60 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	05/30/2014	

Labeler - Vivier Pharma, Inc. (250996550)

Establishment

Name	Address	ID/FEI	Business Operations
Vivier Pharma, Inc.		250996550	manufacture(67226-2140)

Revised: 11/2013 Vivier Pharma, Inc.