

PIGMENT- hydroquinone gel
G.S. COSMECEUTICAL USA, 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.

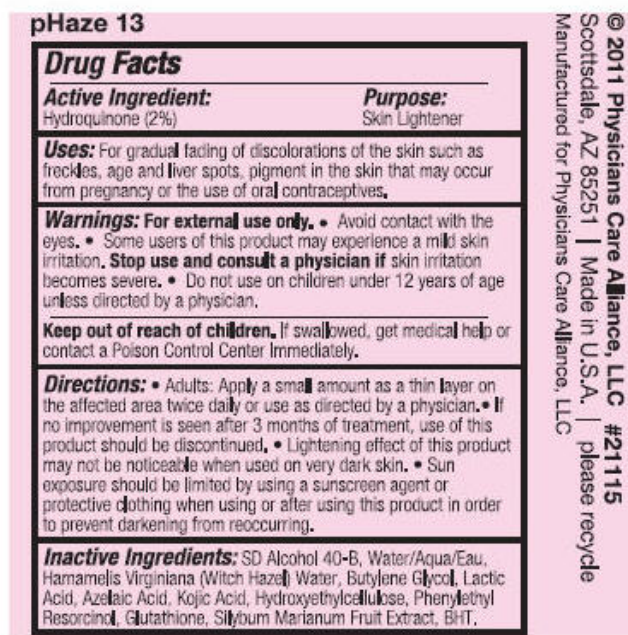
pigment gel®

PRINCIPAL DISPLAY PANEL - 29.5 mL Label

pigment gel®

PCA skin®

1 fl oz/1 oz liq/29.5 mL



PIGMENT			
hydroquinone gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65113-9003
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)		HYDROQUINONE	2 g in 100 mL
Inactive Ingredients			

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
HAMAMELIS VIRGINIANA LEAF WATER (UNII: 8FP93ED6H2)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
LACTIC ACID (UNII: 33X04XA5AT)	
AZELAIC ACID (UNII: F2VW3D43YT)	
KOJIC ACID (UNII: 6K23F1TT52)	
HYDROXYETHYL CELLULOSE (2000 MPAS FOR 1% AQUEOUS SOLUTION) (UNII: S38J6RZN16)	
PHENYLETHYL RESORCINOL (UNII: G37UFG162O)	
GLUTATHIONE (UNII: GAN16C9B8O)	
SILYBUM MARIANUM SEED (UNII: U946SH95EE)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Product Characteristics

Color	YELLOW (LIGHT YELLOW)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65113-9003-1	7.4 mL in 1 BOTTLE, PLASTIC		
2	NDC:65113-9003-2	29.5 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG PRODUCT MANUFACTURED EXCLUSIVELY FOR PRIVATE LABEL DISTRIBUTOR		05/26/2011	

Labeler - G.S. COSMECEUTICAL USA, INC. (017014734)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE

Revised: 11/2011

G.S. COSMECEUTICAL USA, INC.