ULTRA GLOW FADE- hydroquinone cream
Keystone Laboratories

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.

Ultra Glow Fade Cream (2% Hydroquinone and 1.5% Padimate O)

2% Hydroquinone ..... Skin Lightener

1.5% Padimate O.....Subscreen

Keep out of reach of children.

Skin lightener

Skin Lightener

Sunscreen

Warnings:

For external use only. Children under 12 years of age: Do not use unless directed by a doctor. Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor. Avoid contact with eyes, rinse with water to remove. Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin during and after treatment is completed in order to prevent darkening from reoccurring. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Adults: Apply a small amount in a thin layer on the affected area twice daily or as directed by a doctor. If no improvement is seen after 3 months of treatment, use of this product should be discontinued. Lightening effect of this product may not be noticeable on very dark skin.

Other Information: Protect the product in this container from excessive heat and direct sun. For expiration date, please see bottom of jar.

Distributed by

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www.keystone-labs.com

1-800-772-8860 / Memphis, TN 38101-2026

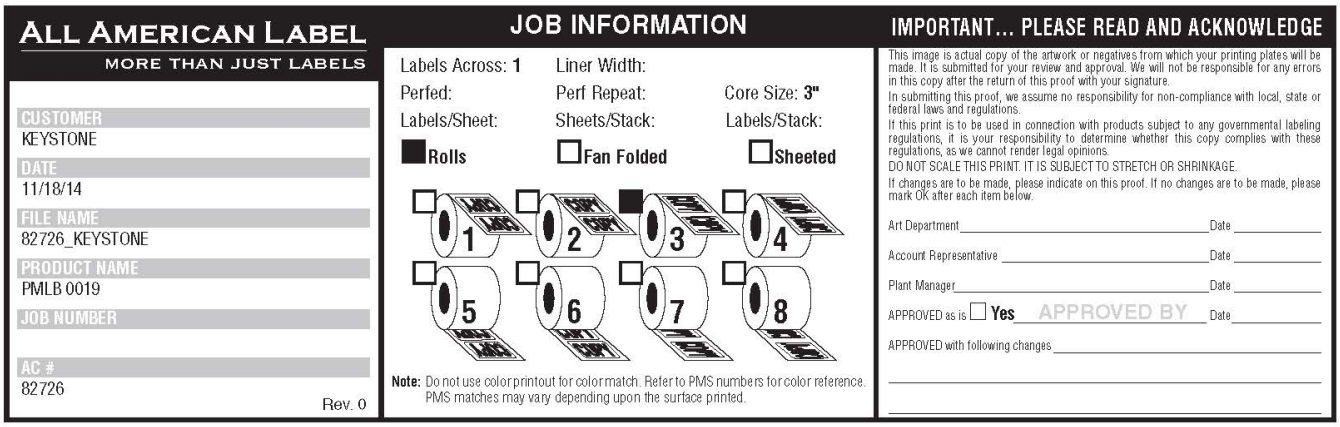
MADE IN U.S.A.

PM-LB 0011

Inactive Ingredients:

water, stearyl stearate, propylene glycol, cetyl alcohol, isopropyl myristate, mineral oil, sodium metabisulfite, fragrance, steareth 20, methylparaben, butylhydoxytoluene, prophyl gallate, sodium sulfite, sodium sulfite, tetrasodium EDTA, propylparaben, citric acid, aloe barbadensis (Leaf Juice)

82726 • Keystone • PM-LB 0019 • Size: 1.5" x 8" • Color: PMS 5215



ULTRA GLOW FADE

hydroquinone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58318-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	2 g in 102 g
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	1.5 g in 102 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM DITHIONATE (UNII: RPF7Z41GAW)	
STEARYL STEARATE (UNII: 5WX2EGD0DK)	
STEARETH-20 (UNII: L0Q8IK9E08)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYL ALCOHOL (UNII: Y4S76JWI15)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58318-008-01	102 g in 1 JAR; Type 0: Not a Combination Product	01/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	01/04/2018	

Labeler - Keystone Laboratories (007017429)

Establishment

Name	Address	ID/FEI	Business Operations
Keystone Laboratories		007017429	manufacture(58318-008)

Revised: 1/2018 Keystone Laboratories