

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, butylhydroxytoluene, propyl gallate, sodium sulfite, sodium sulfite, tetrasodium EDTA, propylparaben, citric acid, aloe barbadensis (Leaf Juice)

Inactive Ingredients: Water, Stearyl Stearate, Propylene Glycol, Cetyl Alcohol, Isopropyl Myristate, Mineral Oil, Sodium Metabisulfite, Fragrance, Steareth 20, Methylparaben, Butylhydroxytoluene, Propyl Gallate, Sodium Sulfite, Tetrasodium EDTA, Propylparaben, Citric Acid, Aloe Barbadensis (Leaf Juice)

ULTRA GLOW

Fade Cream

2% Hydroquinone... Skin Lightener
1.5% Padimate O Sunscreen

NET WT. 3.6 OZ. (102g)

N | Normal Skin

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www.keystone-labs.com
1-800-722-8807, Allentown, PA 18101-2026
MADE IN U.S.A.
PM-LB 0019



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

ALL AMERICAN LABEL	JOB INFORMATION	IMPORTANT... PLEASE READ AND ACKNOWLEDGE
MORE THAN JUST LABELS	Labels Across: 1 Perfed: Labels/Sheet:	<p>This image is actual copy of the artwork or negatives from which your printing plates will be made. It is submitted for your review and approval. We will not be responsible for any errors in this copy after the return of this proof with your signature.</p> <p>In submitting this proof, we assume no responsibility for non-compliance with local, state or federal laws and regulations.</p> <p>If this print is to be used in connection with products subject to any governmental labeling regulations, it is your responsibility to determine whether this copy complies with these regulations, as we cannot render legal opinions.</p> <p>DO NOT SCALE THIS PRINT. IT IS SUBJECT TO STRETCH OR SHRINKAGE.</p> <p>If changes are to be made, please indicate on this proof. If no changes are to be made, please mark OK after each item below.</p> <p>Art Department _____ Date _____</p> <p>Account Representative _____ Date _____</p> <p>Plant Manager _____ Date _____</p> <p>APPROVED as is <input type="checkbox"/> Yes APPROVED BY _____ Date _____</p> <p>APPROVED with following changes _____</p>
CUSTOMER KEYSTONE	Liner Width: Perf Repeat: Sheets/Stack:	
DATE 11/18/14	Core Size: 3" Labels/Stack:	
FILE NAME 82726_KEYSTONE	<input checked="" type="checkbox"/> Rolls <input type="checkbox"/> Fan Folded <input type="checkbox"/> Sheeted	
PRODUCT NAME PMLB 0019		
JOB NUMBER	<p>Note: Do not use colorprintout for color match. Refer to PMS numbers for color reference. PMS matches may vary depending upon the surface printed.</p>	
AC # 82726	Rev. 0	

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: 059QF0K00R)	
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