

## **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.*

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2% Hydroquinone ..... Skin Lightener

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Skin lightener

Ultra Glow Fade Cream

2% Hydroquinone ..... Skin Lightener

#### **ⓧ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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1-800-772-8860 / Memphis, TN 38101-2026

MADE IN U.S.A.

PM-LB 0011

#### **ⓧInactive Ingredients:**

Aqua/Water/Eau, Stearyl Stearate, Glycerol Stearate, Propylene Glycol Alcohol, Isopropyl Myristate, Sodium Metabisulfite, Fragrance, Sodium Sulfite, Steareth 20, Methyl Paraben, Buthydroxytoluene, Propyl Gallate, Tetrasodium EDTA, Propyl Paraben, Citric Acid

**Active Ingredients:** Hydroquinone  
**Inactive Ingredients:** Aqua/Water/Eau, Stearyl Stearate, Glycerol Stearate, Propylene Glycol, Cetyl Alcohol, Isopropyl Myristate, Sodium Metabisulfite, Fragrance, Sodium Sulfite, Steareth 20, Methyl Paraben, Butylhydroxytoluene, Propyl Gallate, Tetrasodium EDTA, Propyl Paraben, Citric Acid.

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 PM-LB 0011

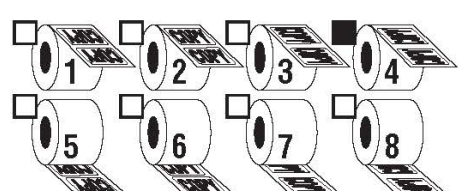
**ULTRAGLOW**  
 Fade Cream  
 2% Hydroquinone...Skin Lightener  
 NET WT. 1.8 OZ. (51g) N | Normal Skin

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**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 sun irritation. If sun 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 sunblocking agent, or protective clothing to cover affected 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.

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

82725C • Keystone • PM-LB 0011 • Size: 1.125" x 6.375" • Color: PMS 5215

ALL AMERICAN LABEL MORE THAN JUST LABELS	JOB INFORMATION	IMPORTANT... PLEASE READ AND ACKNOWLEDGE
<b>CUSTOMER</b> KEYSTONE <b>DATE</b> 12/15/14 <b>FILE NAME</b> 82725_KEYSTONE <b>PRODUCT NAME</b> PMLB 0011 <b>JOB NUMBER</b>  <b>AC #</b> 82725A Rev. 0	<b>Labels Across: 1</b> <b>Liner Width:</b> <b>Perfed:</b> <b>Perf Repeat:</b> <b>Core Size: 3"</b> <b>Labels/Sheet:</b> <b>Sheets/Stack:</b> <b>Labels/Stack:</b> <input checked="" type="checkbox"/> <b>Rolls</b> <input type="checkbox"/> <b>Fan Folded</b> <input type="checkbox"/> <b>Sheeted</b>  <b>Note:</b> Do not use color printout for color match. Refer to PMS numbers for color reference. PMS matches may vary depending upon the surface printed.	<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><b>DO NOT SCALE THIS PRINT. IT IS SUBJECT TO STRETCH OR SHRINKAGE.</b></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 _____            Account Representative _____ Date _____            Plant Manager _____ Date _____            APPROVED as is <input type="checkbox"/> <b>Yes</b>    <b>APPROVED BY</b> _____ Date _____            APPROVED with following changes _____</p>

## ULTRA GLOW FADE

hydroquinone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58318-003
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	1 g in 51 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 METABISULFITE (UNII: 4VON5FNS3C)	
STEARYL STEARATE (UNII: 5WX2EGD0DK)	
STEARETH-20 (UNII: L0Q8IK9E08)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>SODIUM SULFITE</b> (UNII: VTK01UQK3G)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>METHYL ALCOHOL</b> (UNII: Y4S76JWI15)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58318-003-01	51 g in 1 CANISTER; Type 0: Not a Combination Product	01/10/2018	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	01/10/2018	

**Labeler** - Keystone Laboratories (007017429)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Keystone Laboratories		007017429	manufacture(58318-003)

Revised: 1/2018

Keystone Laboratories