

**MIRACLE FADE- hydroquinone cream**  
**Concept Laboratories, 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.*

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**Miracle**  
**Fade Cream**

Drug Facts

**Active ingredient**

Hydroquinone 1.5%

**Purpose**

Skin Lightener

**Uses**

for the gradual fading of dark (brownish) discolorations in the skin such as

- freckles
- age and liver spots
- pigment in the skin that may occur in pregnancy or from the use of oral contraceptives

**Warnings**

For external use only.

- avoid contact with eyes. If eye contact occurs flush thoroughly with water.
- some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor
- do not use on children under 12 years of age unless directed by a doctor
- if pregnant or nursing, seek the advice of a health professional before using

When using this product do not use on cracked, irritated or inflamed skin

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 as a thin layer on the affected area twice daily, or use 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 when used on very dark skin.
- for sensitive skin, test product on a small section of your skin inside your elbow

**Inactive ingredients**

Water (Aqua), Glyceryl Stearate SE, Cetearyl Alcohol, Mineral Oil, Cetareth-20, Isopropyl Myristate,

Glycerin, Petrolatum, Butyrospermum Parkii (Shea Butter), Sodium Metabisulfite, Propylene Glycol, DMDM Hydantoin, Methylparaben, Propylparaben, Citric Acid, Glycolic Acid, Ascorbic Acid, Glycyrrhiza Glabra (Licorice) Root Extract, Disodium EDTA, Fragrance.

### Other Information

- For sensitive skin, test product on a small section of your skin inside your elbow. If no irritation develops after 24 hours proceed with application.
- Close product lid tightly after each use. Cream may darken when exposed to air. Product performance will not be affected.
- Do not use this product in combination with externally applied products containing resorcinol, phenol, salicylic acid or any type of acne product unless directed by a doctor.
- Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

### Questions or comments?

Call 1-888-373-8831 or visit [www.conceptlabs.org](http://www.conceptlabs.org)

Manufactured by Concept Laboratories, Inc., Chicago, IL 60642 (USA)

#BG-U24

### PRINCIPAL DISPLAY PANEL - 113 g Jar Label

*Miracle*

fade creme

Skin Lightening

4oz. (113g)



### MIRACLE FADE

hydroquinone cream

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64058-716
Route of Administration	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	1.695 g in 113 g

## Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0K00R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64058-716-34	113 g in 1 JAR		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part358A	04/29/2014	

**Labeler** - Concept Laboratories, Inc. (962282612)

## Establishment

Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE(64058-716)

Revised: 6/2014

Concept Laboratories, Inc.