DR. LIGHTENING ULTRA-POTENT FACIAL- hydroquinone cream
Clinical Resolution Laboratory, 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.

Dr. Lightening Ultra-Potent Facial Cream

DRUG FACTS

Active Ingredient

Hydroquinone 2%

Purpose

Skin Lightener

Uses:

for the gradual fading of hyperpigmentation spots.

Warnings:

For external use only

When using this product

- avoid contact with eyes.
- some users of this product may experience mild irritation. If skin irritation becomes severe, stop use and consult a doctor.
- for external use only.

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- if skin irritation becomes severe.

if pregnant or breastfeeding,

- consult a doctor before use.

Do not use this product if

children under 12 years of age, unless directed by a doctor

Keep out of reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

Sunburn Alert
The Alpha and Beta Hydroxy Acids (AHA/BHA)in this product may increase sun sensitivity. Wear sunscreen or protective clothing during use to protect against sunburn and for a week afterwards. Continue sun protection after the lightening regimen to avoid UV-induced pigmentations.

Directions

- Adults: apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor.

- Do not use on or around the eye area.
- If no improvement is seen after 3 months of treatment, use of this product should be discontinued. Lightening effect of this product may be noticeable when used on very dark skin.
- 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.

Other Information

store at 20°-25° C (68-77° F)

Inactive Ingredients

Arbutin, Arginine, Azelaic Acid, Carrageenan, Ceteareth-20, Cetearyl Alcohol, Citric Acid, Cyclopentasiloxane, Dimethyl Isosorbide, Disodium EDTA, Fragrance, Glycerin, Glyceryl Stearate, Hydrogenated Polydecene, Isododecane, Kojic Acid, Magnesium Aluminum Silicate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Niacinamide, PEG-100 Stearate, Phenoxyethanol, Purified Water, Salicylic Acid, Sodium Benzoate, Sodium Polyacrylate, Sodium Sulfite, Trideceth-6

Questions or comments?

Call toll free 1(844) 694-0004

Package Labeling:

LABEL SIZE: 3.5 X 4.25 Inches

DRUG FACTS (continued)

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Ebanel™

DR LIGHTENING
ULTRA-POTENT
FACIAL CREAM

2% HYDROQUINONE

VITAMIN C
ALPHA ARBUTIN
NIACINAMIDE
KOJIC ACID
AZELAIC ACID
LACTIC ACID
SALICYLIC ACID

Diminish Dark Spots
Fades Melasma

1.55 oz e 44g

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Manufactured for Ebanel Laboratories Inc.
1400 W. Lambert Rd., Suite D
www.Ebanel.com | Made in USA

DR. LIGHTENING ULTRA-POTENT FACIAL

hydroquinone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63742-025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	

TEA TREE OIL (UNII: VIF565UC2G)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
ARBUTIN (UNII: C5INA23HXF)	
ARGININE (UNII: 94ZLA3W45F)	
AZELAIC ACID (UNII: F2VW3D43YT)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
ISODODECANE (UNII: A8289P68Y2)	
KOJIC ACID (UNII: 6K23F1TT52)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63742-025-01	44 g in 1 TUBE; Type 0: Not a Combination Product	02/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	02/15/2019	

Labeler - Clinical Resolution Laboratory, Inc. (825047942)

Revised: 4/2019 Clinical Resolution Laboratory, Inc.