IDOLE BEAUTY - hydroquinone lotion International Beauty Exchange

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.

Drug Facts

Hydroquinone 2%

Ethylhexyl Methoxycinnamate (Octyl Methoxycinnamate) 0.5%

For external use only

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

Avoid contact with eyes.

Skin Lightener



Drug Facts

Active Ingredients

Purpose

Hydroguinone 2%

Skin Lightener Sun Screen

Octyl Methoxycinnamate 0,5%

Sull Screen

Uses: For the gradual fading of dark (brownish) areas in the skin such as freckles, age and liver spots.

Contains a sunscreen to help prevent darkening from reoccurring.

Warnings: For external use only

This product is not for use in the prevention of sunburn.

Do not use: On children under 12 years of age unless directed by a doctor.

When using this product: Avoid contact with eves.

Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor. Keep out of the 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.

Children under 12 years of age: Do not use 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 after treatment is complete in order to prevent darkening from reoccurring.

Inactive ingredients:

Water (aqua), Glyceryl Stearate, Isopropyl Myristate, Glycerin, Cetearyl Alcohol, Fragrance (Parfum), Tocopheryl Acetate, Allantoin, Ascorbic Acid, Sodium Lauryl Sulfate, Sodium Metabisulfite, Disodium EDTA, Methylparaben, Propylparaben, p-Chloro-m-Cresol.

IDOLE BEAUTY

hydroquinone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66129-430
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
HYDRO Q UINO NE (UNI	I: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	5 mL in 250 mL
OCTINOXATE (UNII: 4)	75P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.25 mL in 250 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
ALLANTO IN (UNII: 344S277G0Z)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
.ALPHATO COPHERO L ACETATE, D- (UNII: A7E6112E4N)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CHLOROCRESOL (UNII: 36W53O7109)	

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66129-430-11	250 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358 A	0 1/0 1/20 11	

Labeler - International Beauty Exchange (966261273)

Establishment				
Name	Address	ID/FEI	Business Operations	
JABONES PARDO SA		462018250	manufacture	

Revised: 5/2011 International Beauty Exchange