TOP WHITE SKIN LIGHTENING - 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.

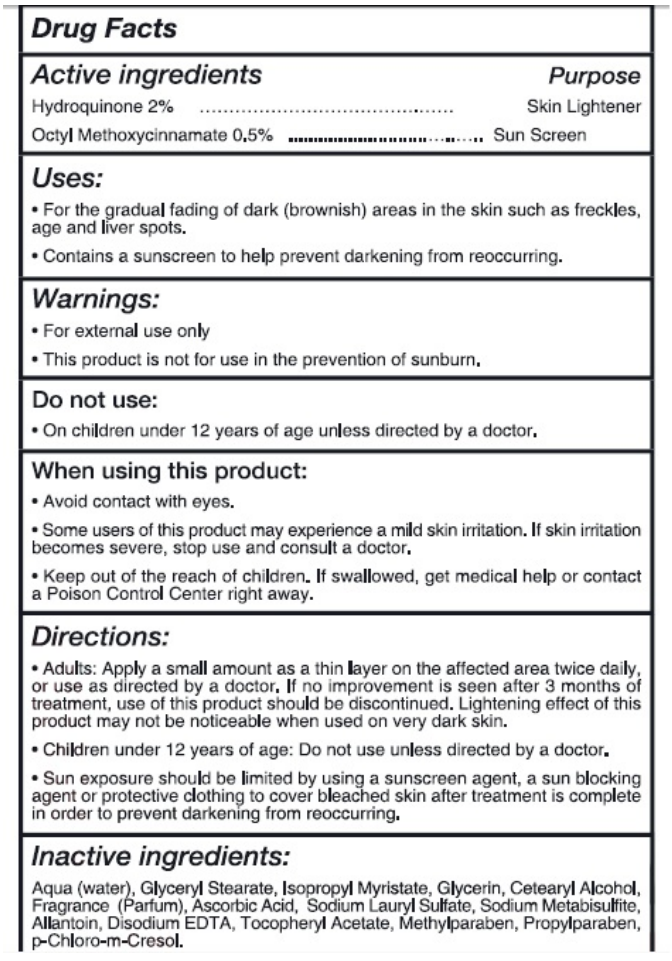
Skin Lightener

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

Apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor

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

WATER,GLYCERYL STEARATE CITRATE, CETOSTEARYL ALCOHOL, GLYCERIN, ISOPROPYL MYRISTATE, ALLANTOIN, ASCORBIC ACID, SODIUM METABISULFITE, .ALPHA.-TOCOPHEROL ACETATE D-, SODIUM LAURYL SULFATE, EDETATE DISODIUM, METHYLPARABEN, PROPYLPARABEN, CHLOROCRESOL



Drug Facts

Active ingredients — **Purpose**

Hydroquinone 2% ..... Skin Lightener

Octyl Methoxycinnamate 0.5% ..... Sun 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 eyes.
- 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:

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

TOP WHITE SKIN LIGHTENING

hydroquinone lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66129-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	10 mL in 500 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.5 mL in 500 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALLANTOIN (UNII: 344S277G0Z)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CHLOROCRESOL (UNII: 36W53O7109)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:66129-123-25	500 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	01/01/2012	

Labeler - International Beauty Exchange (966261273)

Establishment

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

Revised: 4/2012 International Beauty Exchange