

**TOPICLEAR SKIN LIGHTENING - hydroquinone cream**  
**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

<b>Drug Facts</b>	
<b>Active ingredients:</b> Hydroquinone 2%.....Skin Lightener Ethylhexyl Methoxycinnamate (Octyl Methoxycinnamate) 0.5%.....Sun Screen	• 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.
<b>Uses:</b> • 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.	<b>Directions:</b> • 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.
<b>Warnings:</b> • For external use only • This product is not for use in the prevention of sunburn.	• 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.
<b>Do not use:</b> On a children under 12 years of age unless directed by a doctor	<b>Inactive ingredients:</b> Water (Aqua), Glycerin Stearate, Cetearyl Alcohol, Glycerin, Isopropyl Myristate, Fragrance (Parfum), Allantoin, Ascorbic Acid, Sodium Lauryl Sulfate, Sodium Metabisulfite, Disodium EDTA, Sodium Citrate, Methylparaben, Propylparaben, p-Chloro-m-Cresol.
<b>When using this product:</b> • Avoid contact with eyes.	

**TOPICLEAR SKIN LIGHTENING**

hydroquinone cream

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:66 129 -0 10

<b>Route of Administration</b>	TOPICAL
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**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Hydroquinone</b> (UNII: XV74C1N1AE) (Hydroquinone - UNII:XV74C1N1AE)	Hydroquinone	1 g in 50 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	.25 g in 50 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERYL STEARATE CITRATE</b> (UNII: WH8T92A065)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128MIS)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>BETA CAROTENE</b> (UNII: 01YAE03M7J)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>CHLOROCRESOL</b> (UNII: 36W53O7109)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66129-010-31	50 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	01/01/2011	

**Labeler** - International Beauty Exchange (966261273)

## Establishment

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

Revised: 4/2011

International Beauty Exchange