

**TOPICLEAR PARIS - hydroquinone gel**  
**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.*

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**Drug Facts**

Hydroquinone 2%

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, CETOSTEARYL ALCOHOL, GLYCERIN, TROLAMINE, CARBOMER COPOLYMER TYPE A, SODIUM METABISULFITE, EDTATE DISODIUM

<b>Drug Facts</b>		Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
<b>Active Ingredients:</b> Hydroquinone 2%.....	<b>Purpose</b> Skin Lightener	
<b>Uses:</b> For the gradual fading of dark (brownish) areas in the skin such as freckles, age and liver spots.		
<b>Warnings:</b> For external use only.		
<b>Do not use:</b> On children under 12 years of age unless directed by a doctor.		
<b>When using this product:</b> 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.		<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. 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>Inactive Ingredients:</b> Water (Aqua), Glycerine, Acrylates / C10-30 Alkylacrylates Crosspolymer, Triethanolamine, Sodium Metabisulfite, Titanium Dioxide, p-Chloro-m-Cresol, Benzyl Alcohol, Methylchloroisothiazolinone, Methylisothiazolinone.

<b>TOPICLEAR PARIS</b>			
hydroquinone gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66 129-840
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	.6 g in 30 g

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
TROLAMINE (UNII: 9O3K93S3TK)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

**Product Characteristics**

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66 129-840-30	30 g in 1 TUBE		

**Marketing Information**

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

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

Name	Address	ID/FEI	Business Operations
JABONES PARDO SA		4620 18 250	manufacture

Revised: 5/2012

International Beauty Exchange