

**TOPICLEAR - 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

Skin Lightener

Avoid contact with eyes.

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

	<b>Drug Facts</b>					
	<table border="1"><thead><tr><th>Active ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Hydroquinone 2%</td><td>Skin Lightener</td></tr><tr><td>Ethylhexyl Methoxycinnamate (Octyl Methoxycinnamate) 0.5%</td><td>Sun Screen</td></tr></tbody></table> <p><b>Uses:</b></p> <ul style="list-style-type: none"><li>Gradually fades skin discolorations such as age spots, freckles, scars</li><li>Contains a sunscreen to help prevent darkening from reoccurring.</li></ul> <p><b>Warnings:</b></p> <ul style="list-style-type: none"><li>For external use only</li><li>This product is not for use in the prevention of sunburn.</li></ul> <p><b>Do not use:</b></p> <ul style="list-style-type: none"><li>On children under 12 years of age unless directed by a doctor.</li></ul> <p><b>When using this product:</b></p> <ul style="list-style-type: none"><li>Avoid contact with eyes.</li><li>Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor.</li><li>Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</li></ul> <p><b>Directions:</b></p> <ul style="list-style-type: none"><li>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.</li><li>Children under 12 years of age: Do not use unless directed by a doctor.</li><li>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.</li></ul> <p><b>Inactive ingredients:</b> Water (Aqua), Glyceryl Stearate, Isopropyl Myristate, Glycerin, Cetearyl Alcohol, Sodium Lauryl Sulfate, Sodium Metabisulfite, Fragrance (Parfum), Ascorbic Acid, Allantoin, Disodium EDTA, Tocopheryl Acetate, Methylparaben, Propylparaben, p-Chloro-m-Cresol.</p> <p><b>UTILISATIONS:</b> Contre les taches d'hyperpigmentation de la peau. Rend le teint plus clair et uni.</p> <p><b>AVERTISSEMENT:</b> Pour usage externe seulement. Eviter le contact avec les yeux et les lèvres. En cas d'irritation, cesser l'usage. Ne pas utiliser sur les enfants âgés de moins de 12 ans. Ce produit n'est pas pour usage sur prévention de coup de soleil.</p>	Active ingredients	Purpose	Hydroquinone 2%	Skin Lightener	Ethylhexyl Methoxycinnamate (Octyl Methoxycinnamate) 0.5%
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Hydroquinone 2%	Skin Lightener					
Ethylhexyl Methoxycinnamate (Octyl Methoxycinnamate) 0.5%	Sun Screen					
	Made in EU • Distributed by International Beauty Exchange Inc. Miami, FL 33014 Ph: 1800,819,9824 www.topiclearinc.com					
	<b>e 500 ml 16,80 fl.oz</b>					

**TOPICLEAR**  
hydroquinone lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66129-020
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Hydroquinone</b> (UNII: XV74C1N1AE) (Hydroquinone - UNII:XV74C1N1AE)	Hydroquinone	10 mL in 500 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.5 mL in 500 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERYL STEARATE CITRATE</b> (UNII: WH8T92A065)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
<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

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:66129-020-25	500 mL in 1 BOTTLE		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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: 5/2011

International Beauty Exchange