

**IDOLE 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

For the gradual fading of dark 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, TOCOPHERYL ACETATE, SODIUM METABISULFITE, SODIUM LAURYL SULFATE, SODIUM LAURYL SULFATE EDETATE, DISODIUM METHYLPARABEN, PROPYLPARABEN, CHLOROCRESOL



*La Crème Médicale IDOLE rend votre peau plus claire et brillante et obtient des résultats durables. Évitez les taches causées par les effets nocifs du soleil. Élimine les boutons et les taches et protège contre les bactéries.*

**APPLICATION:** Appliquer la Crème Médicale IDOLE sur une peau propre deux fois par jour en insistant sur les taches.

**PRECAUTIONS:** Uniquement pour utilisation externe. Éviter le contact avec les yeux. Arrêter l'utilisation en cas d'irritation de la peau.

La Crema IDOLE cuida su piel, manteniéndola clara y luminosa de modo duradero. Combate los efectos nocivos del sol. Ayuda a eliminar las manchas oscuras y protege contra las bacterias.

**MODO DE EMPLEO:** Aplicar la Crema IDOLE dos veces al día sobre la piel limpia, cubriendo especialmente las zonas con manchas.

**PRECAUCIONES:** Solo para uso externo. Evitar el contacto con los ojos, En caso de irritación interrumpir el tratamiento.

Producto no apto para su comercialización en la Unión Europea.

<p><b>Drug Facts</b></p> <table border="0"> <tr> <td><b>Active ingredients:</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Hydroquinone 2%.....</td> <td>Skin Lightener</td> </tr> <tr> <td>Ethylhexyl Methoxycinnamate 0.5%.....</td> <td>Sun Screen</td> </tr> </table>	<b>Active ingredients:</b>	<b>Purpose</b>	Hydroquinone 2%.....	Skin Lightener	Ethylhexyl Methoxycinnamate 0.5%.....	Sun Screen	<ul style="list-style-type: none"> <li>Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor.</li> </ul> <p>Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>
<b>Active ingredients:</b>	<b>Purpose</b>						
Hydroquinone 2%.....	Skin Lightener						
Ethylhexyl Methoxycinnamate 0.5%.....	Sun Screen						
<p><b>Uses:</b> Gradually fades skin discolorations such as age spots, freckles, scars.</p>	<p><b>Directions:</b></p> <ul style="list-style-type: none"> <li>Clean your skin with IDOLE Soap. Adult and children over 12 years old apply cream evenly to your skin twice a day or as 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 skin after treatment is completed, to prevent darkening from reoccurring.</li> </ul>						
<p><b>Warnings:</b> For external use only</p> <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> <li>This product for the prevention of sunburn.</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>Avoid contact with eyes.</li> </ul>	<p><b>Inactive ingredients:</b></p> <p>Water, Glyceryl Stearate, Cetearyl Alcohol, Glycerin, Isopropyl Myristate, Allantoin, Tocopheryl Acetate, Fragrance, Ascorbic Acid, Sodium Lauryl Sulfate, Sodium Metabisulfite, Disodium EDTA, Sodium Citrate, Methylparaben, Propylparaben, p-Chloro-m-Cresol.</p>						

**IDOLE SKIN LIGHTENING**  
hydroquinone cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66129-410
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	1 g in 50 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	.25 g in 50 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ALLANTOIN (UNII: 344S277G0Z)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
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:66129-410-31	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**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
JABONES PARDO SA		4620 18250	manufacture

Revised: 7/2011

International Beauty Exchange