

**METASOL - 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, ALCOHOL, GLYCERIN, CARBOMER COPOLYMER TYPE A, TROLAMINE, SODIUM METABISULFITE, EDTATE DISODIUM, OENOTHERA BIENNIS

<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>Benzophenone-4 0.1%.....</td> <td>Sun Screen</td> </tr> </table>		<b>Active ingredients:</b>	<b>Purpose</b>	Hydroquinone 2%.....	Skin Lightener	Benzophenone-4 0.1%.....	Sun Screen	<p>• Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor.</p> <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							
Benzophenone-4 0.1%.....	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 Metasol Medicated Soap. Adult and children over 12 years old apply Gel 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></p> <ul style="list-style-type: none"> <li>• For external use only</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> <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 (Aqua), Alcohol denat, Glycerine, Acrylates/C10-30 Alkylacrylates Crosspolymer, Triethanolamine, Sodium Metabisulfite, Fragrance (Parfum), Evening Primerose (Oenothera Biennis) Oil, Disodium EDTA.</p>						

<b>METASOL</b>			
hydroquinone gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66129-540

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

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	1 g in 50 g
BENZOPHENONE (UNII: 701M4TTV9O) (BENZOPHENONE - UNII:701M4TTV9O)	BENZOPHENONE	.05 g in 50 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)	
OENOTHERA BIENNIS (UNII: 76UI55V071)	

**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:66129-540-31	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