

**METASOL 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%

Padimate, O 0.5%

For external use only

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

Avoid contact with eyes.

Skin Lightener

**IMPROVED FORMULA**

TRIPLE ACTIVE Skin Lightening + UV Sunscreen + Primrose oil

**METASOL MEDICATED**

Skin Lightening Cream *For a lighter, brighter skin*

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<b>Drug Facts</b>		<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><b>Active Ingredients:</b></p> <p>Hydroquinone 2%..... Skin Lightener</p> <p>Padimate O. 0.5%..... Sun Screen</p>	<p><b>Purpose</b></p> <p>Skin Lightener</p> <p>Sun Screen</p>	
<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 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></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), Glyceryl Stearate, Cetearyl Alcohol, Glycerin, Isopropyl Myristate, Allantoin, Fragrance (Parfum), Evening Primrose (Oenothera Biennis) oil, Ascorbic Acid, Sodium Lauryl Sulfate, Sodium Metabisulfite, Disodium EDTA, Sodium Citrate, Methylparaben, Propylparaben, p-Chloro-m-Cresol.</p>

**METASOL SKIN LIGHTENING**

hydroquinone cream

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:66 129-510

<b>Route of Administration</b>	TOPICAL
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<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>HYDROQUINONE</b> (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	1 g in 50 g
<b>PADIMATE O</b> (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	.25 g in 50 g

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<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>EVENING PRIMROSE OIL</b> (UNII: 3Q9L08K71N)	
<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: A218C7H9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>CHLOROCRESOL</b> (UNII: 36W53O7109)	

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

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66129-510-31	50 g in 1 TUBE		

<b>Marketing Information</b>			
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)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
JABONES PARDO SA		462018250	manufacture

Revised: 5/2011

International Beauty Exchange