

AFRICAN FORMULA BLACK - 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%

For external use only

Skin Lightener

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

Avoid contact with eyes.

If swallowed, get medical help or contact a Poison Control Center right away.

<p>MODE D'EMPLOI : Appliquer matin et soir sur une peau parfaitement nettoyée. Étaler une petite quantité en couche fine et uniforme sur les endroits les plus foncés de la peau.</p>	<p>Ingédient actif: Hydroquinone 2% Ingédients inactifs: Aqua (Water), Alcohol denat, Glycerine, TEA-Acrylates/C10-30 Alkyl acrylates crosspolymer, Theobroma Cacao, Tocopheryl Acetate, Parfum (Fragrance), Ascorbic Acid, Sodium Metabisulfite, Disodium EDTA, BHT, Iron Oxides.</p>				
<p>AVERTISSEMENT: 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.</p>	<p>MADE IN EU Distributed by International Beauty Exchange, Inc. Miami, FL 33014 • Ph: 1.800.819.9624 www.lbeautyexchange.com</p>				
<p>UTILISATIONS : Contre les taches d'hyperpigmentation de la peau. Rend le teint plus clair et uni.</p>					
 <p>AFRICAN FORMULA[®] Skin Lightening Cream BLACK CREAM</p> <p style="text-align: right;">Net Wt 1.76 oz / 50g</p>					
 <p>AFRICAN FORMULA[®] Crème Éclaircissant CRÈME NOIR</p> <p style="text-align: right;">Net Wt 1.76 oz / 50g</p>					
<p>Drug Facts</p> <table border="1"> <tr> <td>Active Ingredients:</td> <td>Purpose</td> </tr> <tr> <td>Hydroquinone 2%.....</td> <td>Skin Lightener</td> </tr> </table> <p>Uses: For the gradual fading of dark (brownish) areas in the skin such as freckles, age and liver spots.</p> <p>Warnings: For external use only</p> <p>Do not use:</p> <ul style="list-style-type: none"> On children under 12 years of age unless directed by a doctor. <p>When using this product:</p> <ul style="list-style-type: none"> 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. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away. 	Active Ingredients:	Purpose	Hydroquinone 2%.....	Skin Lightener	<p>Directions:</p> <ul style="list-style-type: none"> 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. <p>Inactive Ingredients:</p> <p>Water (Aqua), Alcohol denat, Glycerin, TEA-Acrylates/C10-30 Alkyl acrylates crosspolymer, Cocoa Extract, Tocopheryl Acetate, Fragrance (Parfum), Ascorbic Acid, Sodium Metabisulfite, Disodium EDTA, BHT, Iron Oxides.</p>
Active Ingredients:	Purpose				
Hydroquinone 2%.....	Skin Lightener				

hydroquinone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66129-102
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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
COCOA BUTTER (UNII: 512OYT1CRR)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66129-102-31	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

Revised: 3/2011

International Beauty Exchange