

AFRICAN FORMULA 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

<p>envejecimiento, cicatrices o exposición al sol.</p> <p>Modo de empleo: Lave la piel con jabón African Formula. En adultos y niños mayores de 12 años, aplique la crema dos veces al día según las instrucciones del médico.</p> <p>net weight 1,76 oz / 50 gr</p>		<p>una ligera irritación. En caso de irritación severa deje de usarla y consulte a un médico. Discontinuar el uso si no obtiene resultados después de 3 meses. Durante el periodo de embarazo o lactancia debe consultar a un médico. Manténgase alejado de los niños. En caso de ingestión accidental buscar ayuda médica o contactar a un centro de toxicología.</p> <p>MADE IN EU – Distributed by International Beauty Exchange, Inc. Miami, FL 33014 • Ph: 1.800.819.9824 www.ibeauteyexchange.com</p>							
<p>Usage: Efficace contre les taches de vieillesse, solaires, cicatrices de la peau.</p> <p>Directions: Nettoyez votre peau avec du savon African Formula. L'adulte et les enfants sur 12 ans de appliquent la crème même à votre peau deux fois par jour ou comme dirigée par un docteur.</p> <p>net weight 50g / 1,76 oz</p>		<p>Avertissement: Eviter le contact avec les yeux et les lèvres. En cas d'irritation, cesser l'usage et consultez un docteur. Arrêtez l'utilisation si aucune amélioration n'est vue après 3 mois. Si enceinte ou en allaitant au sein consultez un docteur. Substance hors de portée des enfants. En cas d'ingestion accidentelle, obtenez l'aide médicale ou entrez en contact avec un centre de commande de poison.</p> <p>MADE IN EU – Distributed by International Beauty Exchange, Inc. Miami, FL 33014 Ph: 1.800.819.9824 www.ibeauteyexchange.com</p>							
		<p>AFRICAN FORMULA™ Skin Lightening Cream MAXIMUM STRENGTH SKIN TONE FORMULA Crème pour alléger la peau</p> <p>1.76 oz / 50g e</p>							
<p>Drug Facts</p> <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>Uses:</p> <ul style="list-style-type: none"> Gradually fades skin discolorations such as age spots, freckles, scars. Contains a sunscreen to help prevent darkening from reoccurring. <p>Warnings:</p> <ul style="list-style-type: none"> For external use only This product is not for use in the prevention of sunburn. <p>Do not use: On a children under 12 years of age unless directed by a doctor</p> <p>When using this product:</p> <ul style="list-style-type: none"> Avoid contact with eyes. 		Active ingredients:	Purpose	Hydroquinone 2%.....	Skin Lightener	Ethylhexyl Methoxycinnamate (Octyl Methoxycinnamate) 0.5%.....	Sun Screen	<ul style="list-style-type: none"> 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. <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: Water (aqua), Glycerol Stearate, Cetearyl Alcohol, Glycerin, Isopropyl Myristate, Fragrance (Parfum), Ascorbic Acid, Sodium Lauryl Sulfate, Sodium Metabisulfite, Disodium EDTA, Allantoin, Sodium Citrate, Methylparaben, Propylparaben, p-Chloro-m-Cresol.</p>	
Active ingredients:	Purpose								
Hydroquinone 2%.....	Skin Lightener								
Ethylhexyl Methoxycinnamate (Octyl Methoxycinnamate) 0.5%.....	Sun Screen								

hydroquinone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66 129-10 1
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: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALLANTOIN (UNII: 344S277G0Z)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (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:66 129-101-31	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		4620 18250	manufacture

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International Beauty Exchange