

SH18 - 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.

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, EDETATE DISODIUM



Usage:
 Efficace contre les taches de vieillesse, solaires, cicatrices de la peau.

Directions:
 Nettoyez votre peau avec du savon SH•18. 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.

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.

net weight 50g

MADE IN EU
 For International Beauty Exchange, Inc.
 1592 N.W. 159th Street • Miami, FL 33169
 1.800.819.9824

Drug Facts		<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.
Active Ingredients Hydroquinone 2%	Purpose Skin Lightener	
Uses: Gradually fades skin discolorations such as age spots, freckles, scars.		Directions: <ul style="list-style-type: none"> ■ Clean your skin with SH•18 soap. Adult and children over 12 years old apply cream evenly to your skin twice a day or as directed by a doctor. ■ 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 preventing darkening from reoccurring.
Warnings: <ul style="list-style-type: none"> ■ For External use only. 		
Do not use: <ul style="list-style-type: none"> ■ On children under 12 years of age unless directed by a doctor. 		
When using this product <ul style="list-style-type: none"> ■ Avoid contact with eyes. 		Inactive Ingredients: Water (Aqua), Alcohol Denat, Glycerin, Acrylates / C10-30, Alkylacrylates Crosspolymer, Triethanolamine, Fragrance (Parfum), Sodium Metabisulfite, Disodium EDTA, CI 77891

SH18
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66 129-114
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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)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
TROLAMINE (UNII: 9O3K93S3TK)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66129-114-31	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	06/23/2011	

Labeler - International Beauty Exchange (966261273)

Establishment

Name	Address	ID/FEI	Business Operations
JABONES PARDO SA		462018250	manufacture