

DERMACLAIR 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

For the gradual fading of dark 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, GLYCERYL STEARATE CITRATE, CETOSTEARYL ALCOHOL, GLYCERIN, ISOPROPYL MYRISTATE, ALLANTOIN, ASCORBIC ACID, SODIUM METABISULFITE, SODIUM LAURYL SULFATE, DISODIUM EDTA, METHYL PARABEN, PROPYL PARABEN, CHLOROCRESOL

The image displays the packaging for Dermacclair skin lightening cream. The top section shows the English label: "BEAUTY CREAM FOR DARK SKIN" in green, "DERMACLAIR" in large red letters, and "WITH HYDROQUINONE - NET WEIGHT 1.76 oz" in green. A gold starburst graphic on the left says "NEW CREAM". Below this is the French label: "CRÈME DE BEAUTÉ POUR PEAUX FONCÉES" in green, "DERMACLAIR" in large red letters, and "A L'HYDROQUINONE - POIDS NET 50 g" in green. A gold starburst graphic on the left says "CRÈME NOUVEAU". The bottom section is a "Drug Facts" panel with a green border, containing the following information:

Drug Facts	Purpose
Active ingredients Hydroquinone 2% Skin Lightener Ethylhexyl Methoxycinnamate 0.5% Sun Screen	
Uses: Gradually fades skin discolorations such as age spots, freckles, scars.	
Warnings: ■ For external use only	■ Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a doctor.
Do not use: ■ On children under 12 years of age unless directed by a doctor. ■ This product for the prevention of sunburn.	Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
When using this product: ■ Avoid contact with eyes.	Directions: ■ Clean your skin with Dermacclair 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 prevent darkening from reoccurring.
	Inactive ingredients: Water (Aqua), Glyceryl Stearate, Cetearyl Alcohol, Glycerin, Isopropyl Myristate, Fragrance (Parfum), Allantoin, Ascorbic Acid, Sodium Citrate, Sodium Lauryl Sulfate, Sodium Metabisulfite, Disodium EDTA, Methylparaben, Propylparaben, p-Chloro-m-Cresol.

DERMACLAIR SKIN LIGHTENING

hydroquinone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66619-131
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: 2DMT128MIS)	
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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (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:66619-131-31	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

Revised: 6/2011

International Beauty Exchange