

TOPICLEAR COCOA BUTTER BEAUTY - hydroquinone lotion

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.

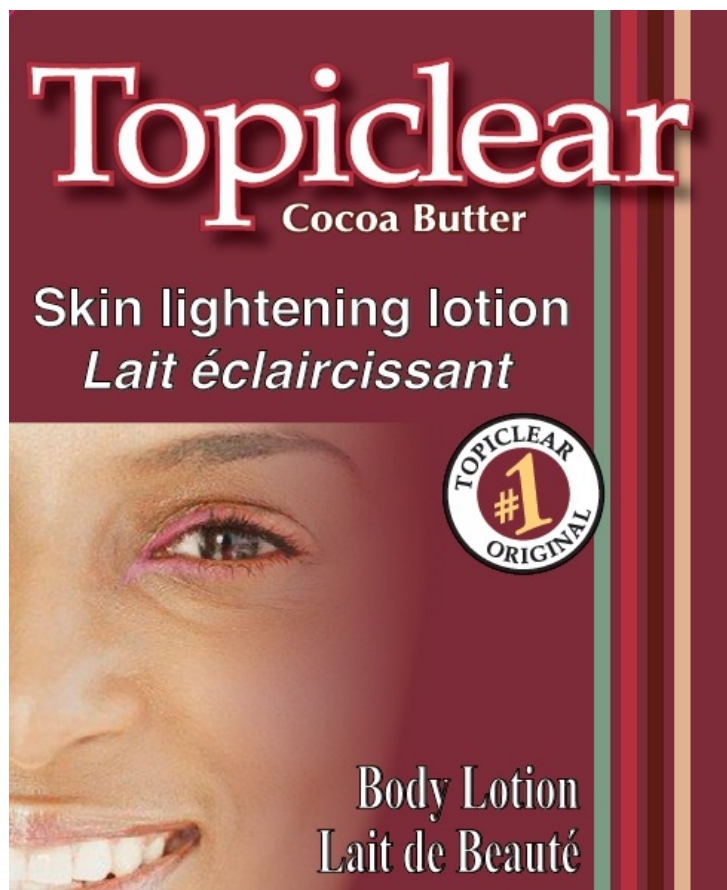
Skin Lightener

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



Drug Facts

Active Ingredients

Hydroquinone 2%
Octyl Methoxycinnamate 0.5%

Purpose
Skin Lightening
Sun Screen

Uses

- For the gradual fading of dark (brownish) areas in the skin such as freckles, age and liver spots.
- Contains a sunscreen to help prevent darkening from reoccurring.

Warnings

- For external use only
- This product is not for use in the prevention of sunburn.

Do not use:

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

When using this product:

- 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.

Directions

- 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.

Inactive Ingredients

Water (Aqua), Glyceryl Stearate, Isopropyl Myristate, Glycerin, Theobroma Cacao (Cocoa Butter), Cetearyl Alcohol, Petrolatum, Fragrance (Parfum), Sodium Lauryl Sulfate, Sodium Metabisulfite, Ascorbic Acid, Allantoin, Disodium EDTA, Tocopheryl Acetate, Methylparaben, Propylparaben, p-Chloro-m-Cresol

UTILISATIONS: Contre les taches d'hyperpigmentation de la peau. Rend le teint plus clair et uni.
AVERTISSEMENT: Pour usage externe seulement. Éviter le contact avec les yeux et les lèvres. En cas d'irritation

TOPICLEAR COCOA BUTTER BEAUTY

hydroquinone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66129-032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	10 mL in 500 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.5 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ALLANTOIN (UNII: 344S277G0Z)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CHLOROCRESOL (UNII: 36W53O7109)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66129-032-25	500 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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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