DARK SPOT LIGHTENING CREAM- hydroquinone cream
Cosmetic Enterprises Ltd.

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.

Dark Spot Lightening Cream

Active ingredient Purpose

Hydroquinone 2% Skin lightener

Use

Lightens dark (brownish) discolorations in the skin such as: freckles, age and liver spots or pigment in the skin that may occur in pregnancy or from the use of oral contraceptives

Keep out of reach of children . If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if

- Skin irritation becomes severe or allergic reaction occurs such as hives, itching, or wheezing

Warnings

For external use only

Allergy alert: contains sulfites that may cause serious allergic type reactions such as hives, itching, wheezing as severe asthma attack in certain susceptible persons.

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 may experience a mild skin irritatiion\

Sunburn alert: This product may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing and limit sun exposure while using this product and for a week afterwards.

If pregnant or breast-feeding, ask a doctor before use.

Directions

- Adults: apply a small amount as a thin layer on the affected area in the evening, or use as directed by a doctor. If no improvement is seen in 3 months of treatment, use of this product should be discontinued. Lightening effect of this product might 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 when using and after using this product in order to prevent darkening from reoccurring.

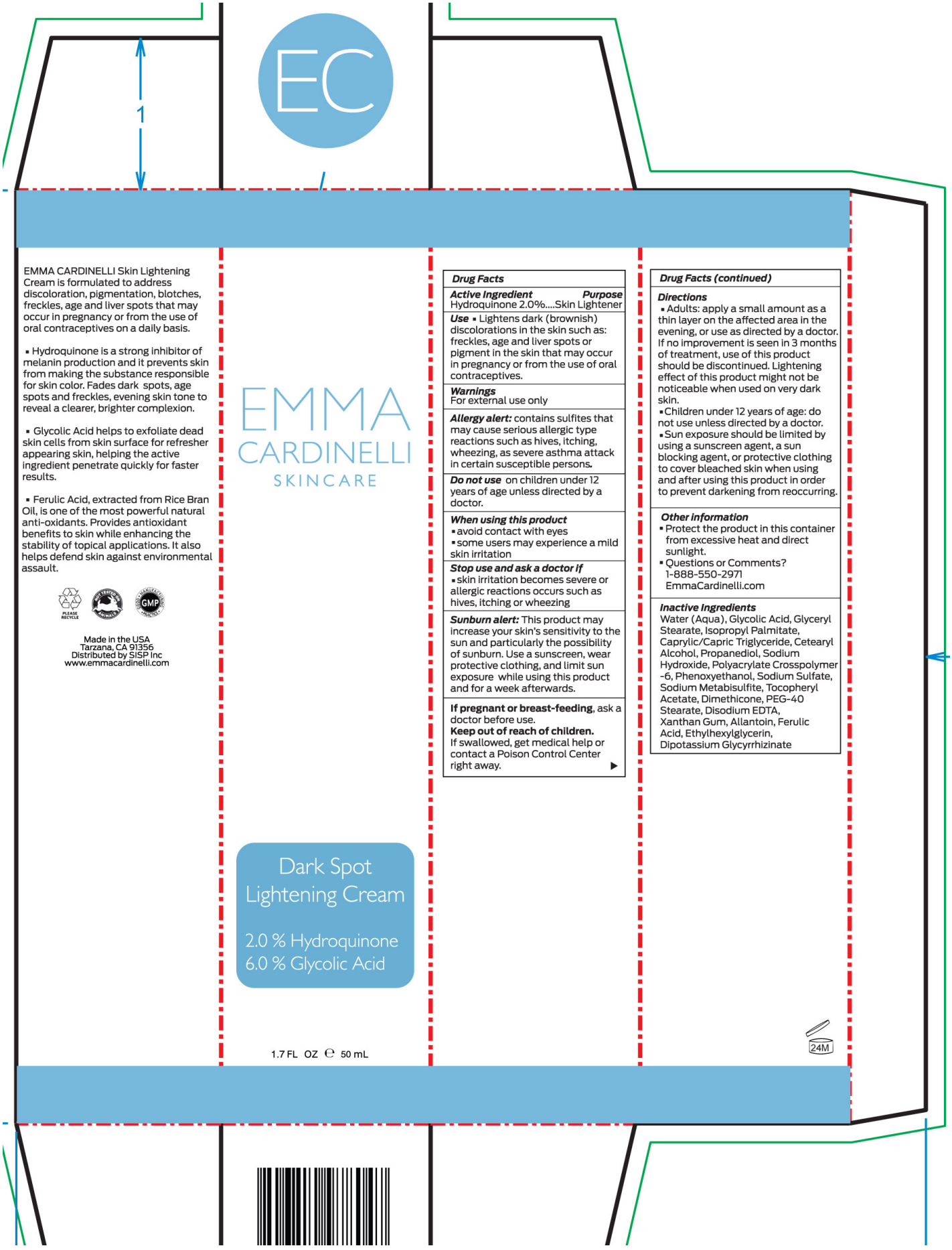
Water (Aqua), Glycolic Acid, Glyceryl Stearate, Isopropyl Palmitate, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Propanediol, Sodium Hydroxide, Polyacrylate Crosspolymer-6, Phenoxyethanol, Sodium Sulfate, Sodium Metabisulfite, Tocopheryl Acetate, Dimethicone, PEG-40 Stearate, Disodium EDTA, Xantan Gum, Allantoin, Ferulic Acid, Ethylhexylglycerin, Dipotassium Glycyrrhizate

Dark Spot Lightening Cream

2% Hydroquinone

6% Glycolic Acid

1.7 FL OZ 50mL



EMMA
CARDINELLI
SKINCARE

Dark Spot
Lightening Cream

2.0 % Hydroquinone
6.0 % Glycolic Acid

1.7 FL. OZ. ℮ 50 mL

Directions for use: Massage evenly over clean face, neck and chest in the evening. Avoid direct contact with eyes. Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

Warning: For external use only. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Active Ingredient: Hydroquinone 2.0% (Skin Lightener)

Inactive Ingredients: Water (Aqua), Glycolic Acid, Glyceryl Stearate, Isopropyl Palmitate, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Propanediol, Sodium Hydroxide, Polyacrylate Crosspolymer-6, Phenoxyethanol, Sodium Sulfate, Sodium Metabisulfite, Tocopheryl Acetate, Dimethicone, PEG-40 Stearate, Disodium EDTA, Xanthan Gum, Allantoin, Ferulic Acid, Ethylhexylglycerin, Dipotassium Glycyrrhizinate

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Tarzana, CA 91356
Distributed by SISP Inc
www.emmacardinelli.com

DARK SPOT LIGHTENING CREAM

hydroquinone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:56152-4002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	2 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPANEDIOL (UNII: 5965N8W85T)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
FERULIC ACID (UNII: AVM951ZWST)	
ALLANTOIN, (+)- (UNII: XDK458E1J9)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
WATER (UNII: 059QF0KO0R)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56152-4002-1	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	12/21/2018	

Labeler - Cosmetic Enterprises Ltd. (017701475)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises Ltd.		217269489	manufacture(56152-4002)

Revised: 12/2018 Cosmetic Enterprises Ltd.