SYMBA SKIN LIGHTENING- hydroquinone cream
Craig Doura LLC

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.

SYMBA® Skin Lightening

Drug Facts

Active Ingredients

Hydroquinone 1.9%

Purpose

Skin Lightening Agent

Uses

Gradually lightens uneven and dark discoloration. Fades freckles, age, and liver spots. Moisturizes the skin. Leaves skin perfumed, soft, and smooth.

For external use only

Warnings

Do not use

- on irritated or broken skin
- on children under 12 years old
- to prevent sunburn
- in combination with products containing Resorcinol, Phenol, or Salicylic Acid

When using this product

- mild irritation or temporary skin darkening may occur
- avoid contact with eyes
- avoid unnecessary sun exposure

Stop use and consult a doctor if

- darkening persists
- irritation becomes severe

If pregnant or breast feeding, consult a doctor before use.

KEEP OUT OF REACH OF CHILDREN. If swallowed, call poison control or get medical attention immediately.

Directions

- for sensitive skin, test overnight on a small section of skin inside the elbow before use
- apply a thin layer to skin on affected areas
- use sunscreen to prevent darkening from recurring
- use twice daily for at least 6 weeks or as directed by doctor

Inactive Ingredients

Water (Aqua), Glyceryl Monostearate, Propylene Glycol, Carrot Seed Oil (Carica Carrot Fruit Extract), Mineral Oil (Paraffinum Liquidum), Cetyl Palmitate, Isopropyl Myristate, Dimethicone, Sodium Lauryl Sulphate, Allantoin, Fragrance (Parfum), Sodium Metabisulfite, Ascorbic Acid (Vitamin C), Propylparaben, Edetate Disodium, FD&C Red No.40.

PRINCIPAL DISPLAY PANEL - 57 g Tube Carton

SYMBA®
SKIN LIGHTENING CREAM

CARROT

With **CARROT Fruit Extract, Vitamin A,** and **Vitamin E**

NDC 71607-300-01

SYMBA SKIN LIGHTENING

hydroquinone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71607-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	19 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Propylene Glycol (UNII: 6DC9Q167V3)	
CARROT SEED OIL (UNII: 595AO13F11)	
Mineral Oil (UNII: T5L8T28FGP)	
Cetyl Palmitate (UNII: 5ZA2S6B08X)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Dimethicone (UNII: 92RU3N3Y1O)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Allantoin (UNII: 344S277G0Z)	
Sodium Metabisulfite (UNII: 4VON5FNS3C)	
Ascorbic Acid (UNII: PQ6CK8PD0R)	
Propylparaben (UNII: Z8IX2SC1OH)	
Edetate Disodium (UNII: 7FLD91C86K)	
FD&C Red No. 40 (UNII: WZB9127XOA)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71607-300-01	1 in 1 CARTON	12/21/2017	
1	NDC:71607-300-57	57 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	12/21/2017	

Labeler - Craig Doura LLC (079084370)

Revised: 12/2017 Craig Doura LLC