

DIVINE DERRIER SKIN BLEACHING 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.

Divine Derrier Skin Bleaching Cream

Active Ingredient Purpose

Hydroquinone 2% Skin lightener

Uses

- Lightens skin discoloration such as freckles, age and liver spots or pigment in the skin that may occur in pregnancy or from the use of oral contraceptions

Keep out of children

If swallowed, get medical help or contact a Poison Control Center immediately.

Stop use and ask a doctor

- If rash occurs

Warnings: for external use only

When using this product

- Avoid contact with eyes
- Limit sun exposure. Protect skin with a Broad-Spectrum sunscreen agent, wear protective clothing to cover bleached skin after treatment to prevent darkening from reoccurring
- Some users of this product may experience mild irritation. If skin irritation becomes severe, stop use and consult a physician
- Do not use on children under 12 years of age unless directed by a physician
- If product consult with a doctor before use
- **If pregnant or breast-feeding**
- Speak with a healthcare professional before use

Sunburn alert

- This product contains an alpha-hydroxy acid (AHA) that 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

Directions

Adult apply a small amount

Inactive Ingredients Water(Aqua), Isopropyl Palmitate, Caprylic/capric Triglyceride, Cetearyl Alcohol, Glyceryl Stearate, Propanediol, Glycolic Acid, Lactic Acid, Kojic Dipalmitate, Sodium Hydroxide, Polyacrylate Crosspolymer-6, Niacinamide, Allantoin, Ferulic Acid, Butylene Glycol, hydrogenated Lecithin, Sodium Oleate, Oligopeptide-68, Dipotassium Glycrrhizate, Sodium Sulfate, Sodium Metabisulfite, Tocopheryl Acetate, Dimethicone, PEG-40 Stearate, Disodium EDTA, Xanthan Gum, Ethylhexylglycerin, Phenoxyethanol, Fragrance.

Divine Derriere Skin Bleaching Cream

Hydroquinone 2% Skin Lightener

50 ml - 1.7fl oz

DRUG FACTS		DRUG FACTS (continued)	
ACTIVE INGREDIENT	PURPOSE	Inactive Ingredients Water (Aqua), Isopropyl Palmate, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Glyceryl Stearate, Propanediol, Glycolic Acid, Lactic Acid, Kojic Dipalmitate, Sodium Hydroxide, Polyacrylate Crosspolymer-6, Niacinamide, Allantoin, Ferulic Acid, Butylene Glycol, Hydrogenated Lecithin, Sodium Oleate, C130-130-60, Dipotassium Glycyphosphate, Sodium Sulfate, Sodium Metabisulfite, Tocopheryl Acetate, Dimethicone, PEG-40 Stearate, Disodium EDTA, Xanthan Gum, Ethylhexylglycerin, Phenoxyethanol, Fragrance	
Hydroquinone 2%	Skin Lightener	Sunburn Alert • This product contains an alpha hydroxy acid (AHA) that 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.	
Uses • Lightens skin discolorations such as freckles, age and liver spots or pigment in the skin that may occur in pregnancy or from the use of oral contraceptives.		Directions • Adults apply a small amount as a thin layer on affected area in the evening, 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 noticed on very dark skin. • Sun exposure should be limited by using a sunscreen agent and protective clothing • Do not use on children under 12 years of age unless directed by a physician	
Warnings: For external use only		Other information • Store at 20-25° C (68-77° F).	
Stop use and ask a doctor • if skin rash occurs		Questions or Comments?	
When using this product • Avoid contact with eyes • Limit sun exposure. Protect skin with a broad-spectrum sunscreen agent, wear protective clothing to cover bleached skin after treatment to prevent darkening from reoccurring • Some users of this product may experience mild irritation. If skin irritation becomes severe, stop use and consult a physician • Do not use on children under 12 years of age unless directed by a physician • If pregnant, consult with a doctor before use		Distributed by Beautiste Brands, LLC 800-336-9286 San Mateo, CA 94403	
If pregnant or breast-feeding • speak with a healthcare professional before use			
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately			



50ml - 1.7 fl oz



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divinederriere.com



DIVINE DERRIER SKIN BLEACHING CREAM

hydroquinone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56 152-4004
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
WATER (UNII: 059QF0K00R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
NIACINAMIDE (UNII: 25X51I8RD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALLANTOIN (UNII: 344S277G0Z)	
FERULIC ACID (UNII: AVM951ZWST)	
SODIUM OLEATE (UNII: 399SL044HN)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
KOJIC DIPALMITATE (UNII: 13N249RWTM)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
LACTIC ACID (UNII: 33X04XA5AT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56152-4004-1	50 mL in 1 JAR; Type 0: Not a Combination Product	01/10/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	01/10/2019	

Labeler - Cosmetic Enterprises Ltd (017701475)

Establishment			
Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises Ltd		017701475	manufacture(56152-4004)

Revised: 1/2019

Cosmetic Enterprises Ltd