

MEDISILKE NIGHT- hydroquinone cream

New GPC, Inc.

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.

Medisilke NIGHT CREAM

Active Ingredient

Hydroquinone 2%

Purpose

Skin bleaching agent.

Uses

For the gradual fading of brownish spots.

Inactive Ingredients

Water, SD Alcohol 40, Glyceryl Stearyl Citrate, Butylene Glycol, Ethylhexyl Palmitate, Methylpropanediol, Behenyl Alcohol, Glycerin, Sodium Hyaluronate, Disodium EDTA, Xanthan Gum, Hydroxyethyl Cellulose, Cetearyl Alcohol, Cetearate-20, BHT, Glyceryl Dilaurate, Dimethicone, Hydroxyethyl Acrylate, Sodium Acryloyl Dimethyl Taurate Copolymer, Squalane, Polysorbate 60, Bambusa Vulgaris Leaf/Stem Extract, Pisum Sativum (Pea) Extract, Glucosamine HCl, Pyrus Malus (Apple) Fruit Extract, Glycine Soja (Soybean) Seed Extract, Retinol, Allyl Methacrylate Crosspolymer, Polysorbate 20, Camellia Sinensis Leaf Extract, Ethylhexylglycerin, Methylisothiazolinone, Phenoxyethanol Capryl Glycol, Potassium Sorbate, Hexylene glycol, Glycyrrhiza Glabra (licorice) Root Extract, Citric Acid Tocopheryl Acetate, Caprylic/Capric Triglyceride, Macadamia Ternifolia Seed Oil Retinyl Palmitate, Zea Mays (Corn Oil), Ubiquinone, Palmitic Acid, Thiocetic Acid, Beta-Carotene, Helianthus Annus (Sunflower) Seed Oil.

Directions

Adults: apply a small amount as a thin layer on the affected area twice daily to affected area or use as directed by a physician. 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.

Warnings

For external use only.

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 physician.

Do not use on children under 12 years age unless directed by a physician.

If swallowed get medical help or contact a poison control center.

Questions or Comments?

Moss Pharmaceuticals, P.O. Box 1426, Port Washington, NY 11060.
www.Medisilke.com

Manufactured by: NEW GPC INC., A1 Farm, EBD, Guyana under license for Moss Pharmaceuticals LLC, USA.

PRINCIPAL DISPLAY PANEL - 20g Tube Carton

Medisilke

NIGHT CREAM

Skin lightening cream / fades brown spots and skin discoloration

20g



MEDISILKE NIGHT

hydroquinone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65588-2230
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 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
DOCOSANOL (UNII: 9G1OE216XY)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
BAMBUSA VULGARIS LEAF (UNII: EMY54R518C)	
BAMBUSA VULGARIS STEM (UNII: SMR633LHTC)	
APPLE (UNII: B423VGH5S9)	
SOYBEAN (UNII: L7HT8F1ZOD)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
RETINOL (UNII: G2SH0XKK91)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MACADAMIA OIL (UNII: 515610SU8C)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CORN OIL (UNII: 8470G57WFM)	
UBIDECARENONE (UNII: EJ27X76M46)	
PALMITIC ACID (UNII: 2V16EO95H1)	
ALPHA LIPOIC ACID (UNII: 73Y7P0K73Y)	
BETA CAROTENE (UNII: 01YAE03M7J)	
HELIANTHUS ANNUUS (UNII: BKJ0J3D1BP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65588-2230-3	1 in 1 CARTON		
1		20 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part358A	12/01/2009	

Labeler - New GPC, Inc. (895025443)

Establishment

Name	Address	ID/FEI	Business Operations
New GPC, Inc.		895025443	MANUFACTURE

Revised: 10/2010

New GPC, Inc.