SKIN LIGHTENING COMPLEX- hydroquinone cream
Vi Medical Products Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

SKIN LIGHTENING COMPLEX

USE

HELPS LIGHTEN DARK PATCHES OF SKIN SUCH AS AGE SPOTS, MELASMA, FRECKLES AND HYPERPIGMENTATION THAT CAN OCCUR AS A RESULT OF PREGNANCY, USE OF ORAL CONTRACEPTIVES OR INJURY TO THE SKIN. RX ONLY. FOR EXTERNAL USE ONLY.

Vi Derm®

SKIN LIGHTENING COMPLEX

HYDROQUINONE 4% CREAM

ACTIVE INGREDIENT — **PURPOSE**
Hydroquinone 4% — Skin Bleaching Cream

INACTIVE INGREDIENTS:
Alpha Arbutin, Arnica Montana Flower Extract, Ascorbic Acid, Azaleic Acid, BHT, Camellia Sinensis Leaf Extract, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Ceteth-10 Phosphate, Cetyl Alcohol, Dicetyl Phosphate, Dimethicone, Glycerin, Glyceryl Stearate, Glycyrrhiza Glabra (Licorice) Root Extract, Isopropyl Palmitate, Kojic Acid Dipalmitate, Malic Acid, Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract, Oridonone, PEG-100 Stearate, Phenoxyethanol, Propylene Glycol, Retinyl Palmitate, Sodium Metabisulfite, Tetrasodium EDTA, Tocopheryl Acetate, Triethanolamine, Water/Aqua

USE
Helps lighten dark patches of skin such as age spots, melasma, freckles and hyperpigmentation that can occur as a result of pregnancy, use of oral contraceptives or injury to the skin. **Rx ONLY. FOR EXTERNAL USE ONLY.**

WARNINGS
Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people. Since this product contains no sunscreen, an effective broad spectrum sun blocking agent should be used and unnecessary solar exposure avoided, or protective clothing should be worn to cover bleached skin in order to prevent re-pigmentation from occurring. Hydroquinone may produce exogenous ochronotic, a gradual blue-black darkening of the skin. If this condition occurs, discontinue treatment and consult your physician.

DIRECTIONS
Apply Hydroquinone 4% to affected areas and rub in well twice daily. Use both morning and night or as directed by a physician.

RX ONLY
FOR EXTERNAL USE ONLY

1.75 FL OZ/50 mL

Distributed by: Vi Aesthetics
Los Angeles, CA 90036 | 855.VI.PEELS www.viaesthetics.com
Made in the USA
CRP-Emerge Europe
Prinsessegracht 20 · 2514 AP The Hague · The Netherlands

Vi Aesthetics

NDC 42192-151-01
B1051903220?

Pediatric Use - Safety and effectiveness for pediatric patients below the age of 12 years have not been established.

ADVERSE REACTIONS
The following adverse reactions have been reported: dryness and fissuring of perioral and infraorbital areas, erythema, and stinging. Occasional hypersensitivity (localized contact dermatitis) may develop. If this occurs, the medication should be discontinued and the

CLINICAL PHARMACOLOGY: Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of tyrosine to 3,4-dihydroxyphenylalanine (dopa) (Denton, C. et al., 1952)1 and suppression of other melanocyte metabolic processes (Jimbow, K. et al., 1974)2. Exposure to sunlight or ultraviolet light will cause repigmentation of bleached areas (Parish, J.A. et al., 1975)3.

physician notified immediately.

OVERDOSAGE

There have been no systemic reactions reported from the use of topical hydroquinone. However, treatment should be limited to relatively small areas of the body at one time, since some patients experience a transient skin reddening and a mild burning sensation which does not preclude treatment.

DOSAGE AND ADMINISTRATION

HYDROQUINONE 4% CREAM should be applied to affected areas and rubbed in well twice daily, in the morning and before bedtime, or as directed by a physician.

If no improvement is seen after 2 months of treatment, use of this product should be discontinued. There is no recommended dosage for pediatric patients under 12 years of age except under the advice and supervision of a physician.

HOW SUPPLIED

HYDROQUINONE 4% CREAM is available in a 1.7 fl oz (50 mL) bottle with (NDC 42192-151-01) Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature]

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. Please NOTE: This is not an Orange Book product and has not been subjected to FDA therapeutic or other equivalency testing. No representation is made as to generic status or bioequivalency. Each person recommending a prescription substitution using this product shall make such recommendation based on his/her professional knowledge and opinion,upon evaluating the

active ingredients, inactive ingredients, excipients and chemical information provided here in.

Manufactured for: VI AESTHETICS Rx Only

PRINCIPAL DISPLAY PANEL - 50 ml. Bottle

NDC 42192-151-01 SKIN LIGHTENING COMPLEX CREAM 1.7 fl oz (50 mL)

FOR EXTERNAL USE ONLY

Active Ingredient: Hydroquinone (4%)

Each gram of HYDROQUINONE 4% CREAM contains 40 mg hydroquinone, in a cream base of Alcohol, Caprylyl Glycine, C13-14 Isoparaffin, Glycerin, Glycolic Acid, Kojic Acid, Laureth-7,

Lecithin, Polyacrylamide, Purified Water, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Squalene and Xanthan Gum.

Inactive Ingredients: Alpha Arbutin, Arnica Montana Flower Extract, Ascorbic Acid, Azelaic Acid, BHT, Camellia Sinensis Leaf Extract, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Ceteth-10 Phosphate, Cetyl Alcohol, Dicetyl Phosphate, Dimethicone, Glycerin, Glyceryl Stearate, Glycyrrhiza Glabra (Licorice) Root Extract, Isopropyl Palmitate, Kojic Acid

INDICATIONS AND USAGE: For the gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile

lentigines, and other unwanted areas of melanin hyperpigmentation.

CONTRAINDICATIONS: Prior history of sensitivity or allergic reaction to hydroquinone or to any of the ingredients of the product. The safety of topical hydroquinone use during pregnancy or for children (12 years and under) has not been established.

WARNINGS: Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic

episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people. Since this product contains no sunscreen, an effective broad spectrum sun blocking agent should be used and unnecessary solar exposure avoided, or protective clothing should be worn to cover bleached skin in order to prevent repigmentation from occurring. Hydroquinone may produce exogenous

ochronosis, a gradual blue-black darkening of the skin. If this condition occurs, discontinue treatment and consult your physician.

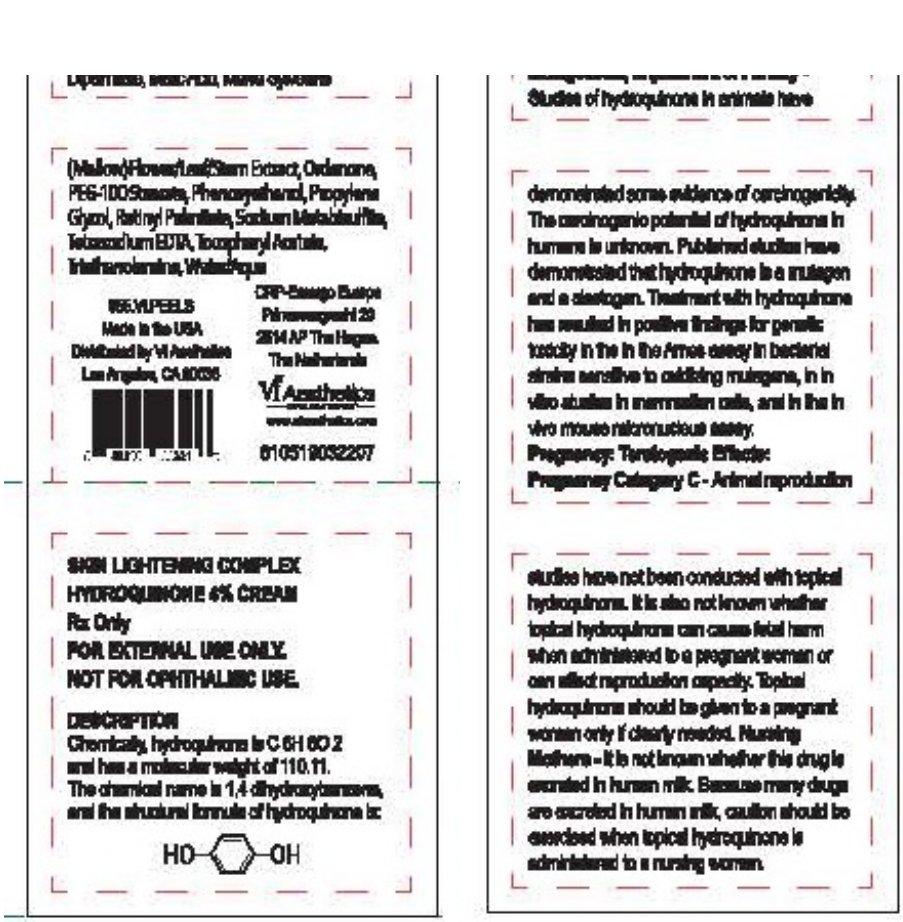
PRECAUTIONS (see WARNINGS)

General - Test for skin sensitivity before using by applying a small amount to an unbroken patch of skin; check within 24 hours. Minor redness is not a contraindication, but where there is itching or vesicle formation or excessive inflammatory response further treatment is not advised. Close patient

supervision is recommended.

Hydroquinone is a skin bleaching agent which may produce unwanted cosmetic effects if not used as directed. The physician should be familiar with the contents of this insert before prescribing or dispensing this medication. Information for Patients - Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight sustains melanocytic activity. To prevent repigmentation, during treatment and maintenance therapy, sun exposure on treated

skin should be avoided by application of a broad spectrum sunscreen (SPF 15 or greater) or by use of protective clothing. Avoid contact with eyes and mucous membranes. Keep this and all medications out of reach of children. In case of accidental ingestion, call a physician or a poison control center immediately. Drug Interactions - Patients are cautioned on concomitant use of medications that are known to be photosensitizing. Carcinogenesis,



SKIN LIGHTENING COMPLEX

hydroquinone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70484-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	4 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ARBUTIN (UNII: C5INA23HXF)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
AZELAIC ACID (UNII: F2VW3D43YT)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
KOJIC DIPALMITATE (UNII: 13N249RWTM)	
MALIC ACID (UNII: 817L1N4CKP)	
MALVA SYLVESTRIS FLOWERING TOP (UNII: X1U1U0N90J)	
METHYL HYDROGENATED ROSINATE (UNII: 13DHA19W9N)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70484-101-12	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/29/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/28/2019	

Labeler - Vi Medical Products Inc. (063910521)

Registrant - Vi Medical Products Inc. INC (063910521)

Establishment

Name	Address	ID/FEI	Business Operations
MICRO CONNECTION ENTERPRISES INC		144297160	manufacture(70484-101)

Revised: 8/2019 Vi Medical Products Inc.