HYDROQUINONE 4%- hydroquinone cream
Acella Pharmaceuticals, LLC

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.

HYDROQUINONE 4% CREAM

Skin Bleaching Cream
Rx Only
FOR EXTERNAL USE ONLY
NOT FOR OPHTHALMIC USE

DESCRIPTION

Each gram of **HYDROQUINONE 4% CREAM** contains 40 mg hydroquinone, in a cream base of Alcohol, Capryloyl Glycine, C13-14 Isoparaffin, Glycerin, Glycolic Acid, Kojic Acid, Laureth-7, Lecithin, Polyacrylamide, Purified Water, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Squalane and Xanthan Gum.

Chemically, hydroquinone is $C_6H_6O_2$ and has a molecular weight of 110.11. The chemical name is 1,4 dihydroxybenzene, and the structural formula of hydroquinone is:

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 (Parrish, J.A. et al., 1978)3.

INDICATIONS AND USAGE

HYDROQUINONE 4% CREAM is indicated 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. The majority of patients developing this condition are Black, but it may also occur in Caucasians and Hispanics.

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, Mutagenesis, Impairment of Fertility -

Studies of hydroquinone in animals have demonstrated some evidence of carcinogenicity. The carcinogenic potential of hydroquinone in humans is unknown.

Published studies have demonstrated that hydroquinone is a mutagen and a clastogen. Treatment with hydroquinone has resulted in positive findings for genetic toxicity in the Ames assay in bacterial strains sensitive to oxidizing mutagens, in in vitro studies in mammalian cells, and in the in vivo mouse micronucleus assay.

Pregnancy:

Teratogenic Effects:

Pregnancy Category C -

Animal reproduction studies have not been conducted with topical hydroquinone. It is also not known whether topical hydroquinone can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Topical hydroquinone should be given to a pregnant woman only if clearly needed.

Nursing Mothers -

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when topical hydroquinone is administered to a nursing woman.

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 paranasal and infraorbital areas, erythema, and stinging. Occasional hypersensitivity (localized contact dermatitis) may develop. If this occurs, the medication should be discontinued and the 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 oz (28.35 g) tube 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 herein.

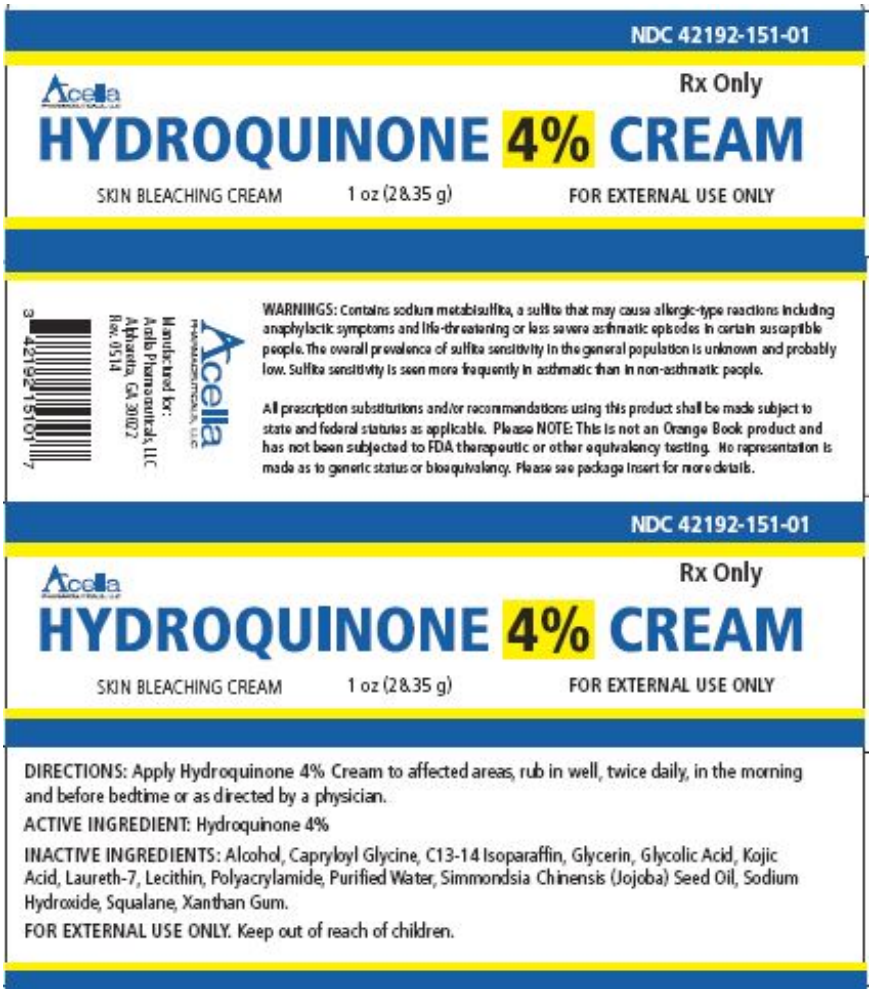
Manufactured for:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30022
Rev. 0614

PRINCIPAL DISPLAY PANEL - 28.35 g Tube Carton

NDC 42192-151-01

Acella
Pharmaceuticals, LLC **Rx Only**

SKIN BLEACHING CREAM **1 oz (28.35 g)** **FOR EXTERNAL USE ONLY**



HYDROQUINONE 4%

hydroquinone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-151
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CAPRYLOYL GLYCINE (UNII: 8TY5YO42NJ)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
KOJIC ACID (UNII: 6K23F1TT52)	
LAURETH-7 (UNII: Z95S6G8201)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYACRYLAMIDE (CROSSLINKED; 0.01-0.2 MOLE PERCENT BISACRYLAMIDE) (UNII: RHA9LWJ494)	
WATER (UNII: 059QF0KO0R)	
JOJOBA OIL (UNII: 724GKU717M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SQUALANE (UNII: GW89575KF9)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-151-01	1 in 1 CARTON	09/10/2014	
1		28.35 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
unapproved drug other		09/10/2014	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-151)

Revised: 9/2018 Acella Pharmaceuticals, LLC