OLIVIA QUIDO BLEMISH ERASER- hydroquinone cream
O Skin Care 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.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BLEMISH ERASER safely and effectively. See full prescribing information for BLEMISH ERASER.

OLIVIA QUIDO FIRM & FADE I Cream (hydrocortisone, hydroquinone, tretinoin) cream, 1%/8%/0.1% for topical use. for topical use

Initial U.S. Approval: XXXX

INDICATIONS AND USAGE

BLEMISH ERASER is a hydroquinone (a melanin synthesis inhibitor) that is indicated for the gradual bleaching of hyperpigmented skin conditions age and liver spots, freckles, and other unwanted areas of melanin hyperpigmentation, in the presence of measures for sun avoidance, including the use of sunscreen. (1) (1)

DOSAGE AND ADMINISTRATION

2 DOSAGE AND ADMINISTRATION
Gently wash the face and neck with a mild cleanser. Rinse and pat the skin dry. Apply a thin film of BLEMISH ERASER to the affected area once daily at night or as directed by a doctor.
During the day, use O Skin Sunscreen SPF-50, and wear protective clothing. Avoid sunlight exposure to prevent repigmentation.
BLEMISH ERASER is for topical use only. It is not for oral, ophthalmic, or intravaginal use.
(2)

DOSAGE FORMS AND STRENGTHS

Cream, 2%. (3)
Each gram of BLEMISH ERASER contains 20.0 mg of hydroquinone in a cream base. (3) (3)

CONTRAINDICATIONS

(4)
BLEMISH ERASER is contraindicated in individuals with a history of hypersensitivity to this product or any of its components.. (4) (4)

WARNINGS AND PRECAUTIONS

If anaphylaxis, asthma or other clinically significantly hypersensitivity reactions occur, institute appropriate therapy and discontinue BLEMISH ERASER. Allergic contact dermatitis may also occur. (5.1)

BLEMISH ERASER contains hydroquinone, which may produce exogenous ochronosis, a gradual blue-black darkening of the skin, the occurrence of which should prompt discontinuation of therapy. (5.2) (5)

ADVERSE REACTIONS

In case of adverse reaction, call a doctor. (6) (6)
(6)
To report SUSPECTED ADVERSE REACTIONS, contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. (6)

USE IN SPECIFIC POPULATIONS

BLEMISH ERASER should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (8.1) (8)

Revised: 5/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

1.1Indication

BLEMISH ERASER is a combination of hydrocortisone (a corticosteroid), hydroquinone (a melanin synthesis inhibitor), and a tretinoin (a retinoid) that is indicated for the gradual bleaching of hyperpigmented skin conditions age and liver spots, freckles, and other unwanted areas of melanin hyperpigmentation, in the presence of measures for sun avoidance, including the use of sunscreen.

1.2 Limitations of Use

The safety and efficacy of BLEMISH ERASER in pregnant women and nursing mothers have not been established.

2 DOSAGE AND ADMINISTRATION

Gently wash the face and neck with a mild cleanser. Rinse and pat the skin dry. Apply a thin film of BLEMISH ERASER to the affected area once daily at night or as directed by a doctor.

During the day, use O Skin Sunscreen SPF-50, and wear protective clothing. Avoid sunlight exposure to prevent repigmentation.

BLEMISH ERASER is for topical use only. It is not for oral, ophthalmic, or intravaginal use.

3 DOSAGE FORMS AND STRENGTHS

Cream, 2%.

Each gram of BLEMISH ERASER contains 20.0 mg of hydroquinone in a cream base. (3)

BLEMISH ERASER is contraindicated in individuals with a history of hypersensitivity to this product or any of its components.. (4)

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity

If anaphylaxis, asthma or other clinically significantly hypersensitivity reactions occur, institute appropriate therapy and discontinue BLEMISH ERASER. Allergic contact dermatitis may also occur.

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.

5.2 Exogenous Ochronosis
BLEMISH ERASER contains hydroquinone, which may produce exogenous ochronosis, a gradual blue-black darkening of the skin, the occurrence of which should prompt discontinuation of therapy. Most patients developing this condition are Black, but it may also occur in Caucasians and Hispanics.

5.3. Effects on Endocrine System

Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced by systemic absorption of topical corticosteroid while treatment. If HPA axis suppression is noted, the use of BLEMISH ERASER should be discontinued. Recovery of HPA axis function generally occurs upon discontinuation of topical corticosteroids.

5.4 Cutaneous Reactions
BLEMISH ERASER contains hydroquinone that may cause mild to moderate irritation. Local irritation, such as skin reddening, peeling, mild burning sensation, dryness, and pruritus may be expected at the site of application. Transient skin reddening or mild burning sensation does not preclude treatment. If a reaction suggests hypersensitivity or chemical irritation, discontinue use of the medication and call a doctor.
Patients should avoid medicated or abrasive soaps and cleansers, soaps and cosmetics with drying effects, products with high concentrations of alcohol and astringents, and other irritants or keratolytic drugs while on BLEMISH ERASER treatment. Avoid use of medications that are known to be photosensitizing.

No systemic adverse reactions have been reported. Occasional hypersensitivity (localized contact dermatitis) may occur, in which case the medication should be discontinued and the physician notified immediately.

7 DRUG INTERACTIONS
Patients should avoid medicated or abrasive soaps and cleansers, soaps and cosmetics with drying effects, products with high concentration of alcohol and astringent, and other irritants or keratolytic drugs while on BLEMISH ERASER Cream treatment. Patients are cautioned on concomitant use of medications that are known to be photosensitizing.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects: Pregnancy Category C

In general, use of drugs should be reduced to a minimum in pregnancy. If a patient has been inadvertently exposed to BLEMISH ERASER in pregnancy, she should be counseled on the risk of teratogenesis due to this exposure. The risk of teratogenesis due to topical exposure to BLEMISH ERASER may be considered low. However, exposure during the period of organogenesis in the first trimester is theoretically more likely to produce adverse outcome than in later pregnancy.

8.3 Nursing Mothers

Corticosteroids, when systemically administered, appear in human milk. It is not known whether topical application of BLEMISH ERASER could result in sufficient systemic absorption to produce detectable quantities of hydroquinone in human milk. Because many drugs are secreted in human milk, caution should be exercised when BLEMISH ERASER is administered to a nursing woman. Care should be taken to avoid contact

between the infant being nursed and BLEMISH ERASER.

8.4 Pediatric Use

Safety and effectiveness of BLEMISH ERASER in pediatric patients have not been established.

8.5 Geriatric Use

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

10 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.

11 DESCRIPTION

BLEMISH ERASER contains 2% of hydroquinone, USP, in a cream base for topical application.

Hydroquinone is a melanin synthesis inhibitor. It is prepared from the reduction of p-benzoquinone with sodium bisulfite. It occurs as fine white needles that darken on exposure to air. The chemical name for hydroquinone is: 1,4-benzenediol. The molecular formula is $C_6H_6O_2$ and molecular weight is 110.11. Hydroquinone has the following structural formula:

BLEMISH ERASER contains Active: 2% (20 mg) Hydroquinone. Inactive: 4-Butylresorcinol, Aloe Barbadensis Leaf Juice, BHT, C13-14 Isoparaffin, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Oleosomes, Ceramide-NP, Cetyl Palmitate, Cetyl PEG/PPG-10/1 Dimethicone, Citric Acid, Diazolidinyl Urea, Dimethyl Isosorbide, Glycerin, Hexyl Laurate, Iodopropynyl Butylcarbamate, Kojic Acid, Laureth-23, Laureth-7, Maltodextrin, Phenoxyethanol, Polyacrylamide, Polyglyceryl-4 Isostearate, Polysorbate 20, Retinol, Silica, Sodium Hyaluronate, Sodium Hydroxide, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Trideceth-6 Phosphate, Triethylene Glycol, Water/Aqua.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of the active ingredients in BLEMISH ERASER in the treatment of melasma is unknown.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

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

Mutagenesis

Mutagenicity studies were not conducted with this combination of active ingredients. 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. Tretinoin has been shown to be negative for mutagenesis in the Ames assay. Additional information regarding the genetic toxicity potential of tretinoin is not available.

Impairment of Fertility

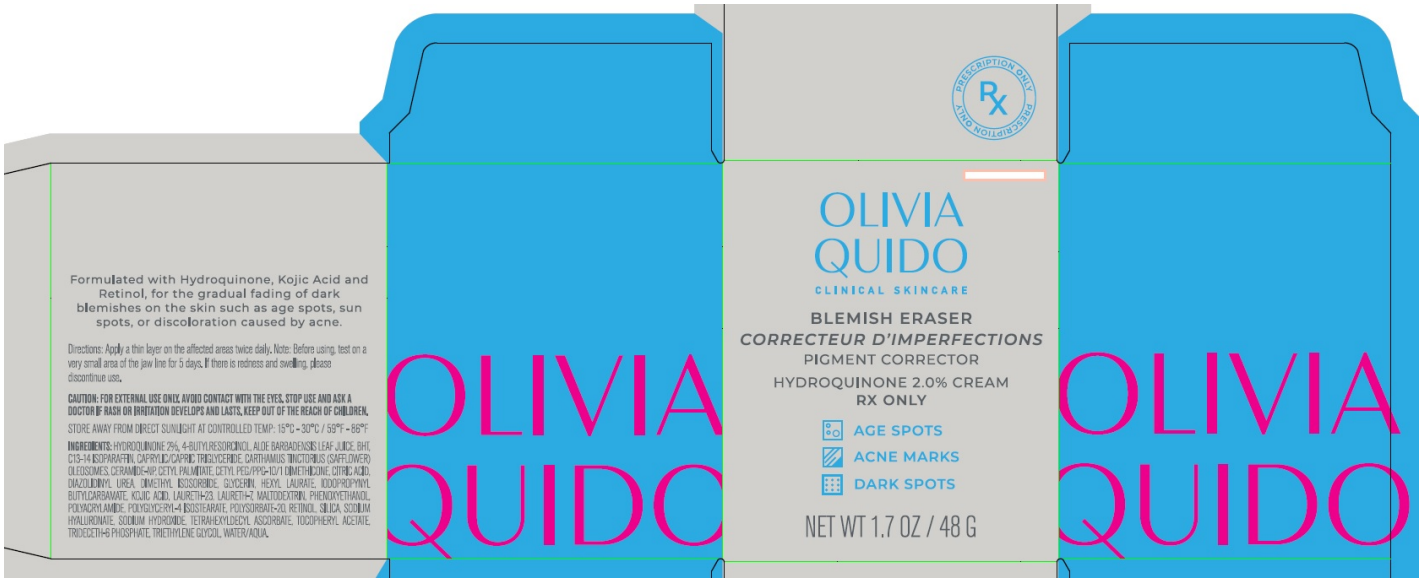
No studies of fertility and early embryonic toxicity of this drug product has been performed.

16 HOW SUPPLIED

BLEMISH ERASER is light yellow in color, and supplied in 48 g jar, NDC 71421-801-30.

Storage: Keep tightly closed. Store at 25°C (77°F); excursions permitted to 15°C – 30°C (59°F – 86°F) away from direct sunlight. KEEP REFRIGERATED.

17 PATIENT COUNSELING INFORMATION
See FDA-approved patient labeling (Patient Information).
Inform patients of the following:
• Advise patients to change to non-hormonal forms of birth control, if hormonal methods are used.
• Use BLEMISH ERASER as directed by the health care provider and do not use BLEMISH ERASER for any disorder other than that for which it is prescribed.
• Avoid exposure to sunlight, sunlamp, or ultraviolet light. Patients who are consistently exposed to sunlight or
skin irritants either through their work environment or habits should exercise particular caution. Use sunscreen
and protective covering (such as the use of a hat) over the treated areas. Sunscreen use is an essential aspect
of melasma therapy, as even minimal sunlight sustains melanocytic activity.
• Weather extremes, such as heat or cold, may be irritating to patients treated with BLEMISH ERASER. Because of the drying effect of this medication, a moisturizer may be applied to the face in the morning after washing.
• Keep BLEMISH ERASER away from the eyes, nose, angles of the mouth, or open wounds
because these areas are more sensitive to the irritant effect. If local irritation persists or becomes severe,
discontinue application of the medication and consult your health care provider. Seek medical attention if you
experience allergic contact dermatitis, blistering, crusting, and severe burning or swelling of the skin and irritation
of the mucous membranes of the eyes, nose, and mouth.
• If the medication is applied excessively, marked redness, peeling, or discomfort may occur.
• Wash your hands after each application.



OLIVIA QUIDO BLEMISH ERASER

hydroquinone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71421-801
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	0.02 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
HYALURONIC ACID (UNII: S270N0TRQY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
WATER (UNII: 059QF0KO0R)	
TRIETHYLENE GLYCOL (UNII: 3P5SU53360)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
LAURETH-7 (UNII: Z95S6G8201)	

CERAMIDE NP (UNII: 4370DF050B)	
TRIDECETH-6 PHOSPHATE (UNII: NKT96BX1OC)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
KOJIC ACID (UNII: 6K23F1TT52)	
RETINOL (UNII: G2SH0XKK91)	
4-BUTYLRESORCINOL (UNII: 2IK4UQ3ZGA)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71421-801-30	1 in 1 BOX	05/04/2022	05/04/2027
1		48 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/04/2022	05/04/2027

Labeler - O Skin Care LLC (021275401)

Revised: 6/2022 O Skin Care LLC