OLIVIA QUIDO FIRM AND FADE I- hydrocortisone, hydroquinone, tretinoin cream
O Skin Pharmaceutical Corporation

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 OLIVIA QUIDO FIRM & FADE I Cream safely and effectively. See full prescribing information for OLIVIA QUIDO FIRM & FADE I Cream.

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

OLIVIA QUIDO FIRM & FADE I Cream 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) (1)

DOSAGE AND ADMINISTRATION

Apply a thin film to the affected area once daily at night or as directed by a doctor. (2)
During the day, use O Skin Sunscreen SPF-50, and wear protective clothing. Avoid sunlight exposure. (2)
(2)

DOSAGE FORMS AND STRENGTHS

Cream, 1%/8%/0.1%. Each gram of OLIVIA QUIDO FIRM & FADE I Cream contains 10.0 mg of hydrocortisone, 80.0 mg of hydroquinone, and 1.0 mg of tretinoin. (3) (3)

CONTRAINDICATIONS

(4)
OLIVIA QUIDO FIRM & FADE I Cream 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 OLIVIA QUIDO FIRM & FADE I Cream. Allergic contact dermatitis may also occur. (5.1)
OLIVIA QUIDO FIRM & FADE I Cream 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

OLIVIA QUIDO FIRM & FADE I Cream contains the teratogen, tretinoin, which may cause embryofetal death, altered fetal growth, congenital malformations, and potential neurologic deficits. OLIVIA QUIDO FIRM & FADE I Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (8.1) (8)

Revised: 9/2019

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

OLIVIA QUIDO FIRM & FADE I Cream 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.

The safety and efficacy of OLIVIA QUIDO FIRM & FADE I Cream in pregnant women and nursing mothers have not been established.

Gently wash the face and neck with a mild cleanser. Rinse and pat the skin dry. Apply a thin film of OLIVIA QUIDO FIRM & FADE I Cream 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.

OLIVIA QUIDO FIRM & FADE I Cream is for topical use only. It is not for oral, ophthalmic, or intravaginal use.

Cream, 1%/8%/0.1%.

Each gram of OLIVIA QUIDO FIRM & FADE I Cream contains 10.0 mg of hydrocortisone, 80.0 mg of hydroquinone, and 1.0 mg of tretinoin in a light yellow, hydrophilic cream base.

OLIVIA QUIDO FIRM & FADE I Cream is contraindicated in individuals with a history of hypersensitivity to this product or any of its components.

If anaphylaxis, asthma or other clinically significantly hypersensitivity reactions occur, institute appropriate therapy and discontinue OLIVIA QUIDO FIRM & FADE I Cream. 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

OLIVIA QUIDO FIRM & FADE I Cream 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 OLIVIA QUIDO FIRM & FADE I Cream should be discontinued. Recovery of HPA axis function generally occurs upon discontinuation of topical corticosteroids.

5.4 Cutaneous Reactions

OLIVIA QUIDO FIRM & FADE I Cream contains hydroquinone and tretinoin 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 OLIVIA QUIDO FIRM & FADE I Cream 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 OLIVIA QUIDO FIRM & FADE I 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 OLIVIA QUIDO FIRM & FADE I Cream in pregnancy, she should be counseled on the risk of teratogenesis due to this exposure. The risk of teratogenesis due to topical exposure to OLIVIA QUIDO FIRM & FADE I Cream 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.

Tretinoin is considered to be highly teratogenic upon systemic administration. Animal

reproductive studies are not available with topical hydroquinone. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

8.3 Nursing Mothers

Corticosteroids, when systemically administered, appear in human milk. It is not known whether topical application of OLIVIA QUIDO FIRM & FADE I Cream could result in sufficient systemic absorption to produce detectable quantities of hydrocortisone, hydroquinone, or tretinoin in human milk. Because many drugs are secreted in human milk, caution should be exercised when OLIVIA QUIDO FIRM & FADE I Cream is administered to a nursing woman. Care should be taken to avoid contact between the infant being nursed and OLIVIA QUIDO FIRM & FADE I Cream.

8.4 Pediatric Use

Safety and effectiveness of OLIVIA QUIDO FIRM & FADE I Cream 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

OLIVIA QUIDO FIRM & FADE I Cream contains 1% of hydrocortisone, USP, 8% of hydroquinone, USP, and 0.1% of tretinoin, USP, in a light yellow, hydrophilic cream base for topical application.

Hydrocortisone is a white to practically white crystalline powder. Chemically, hydrocortisone is pregn-4-ene-3,20-dione, 11, 17,21-trihydroxy-, (11β)-. Its molecular formula is $C_{21}H_{30}O_5$; its molecular weight is 362.46; its Chemical Abstract Service (CAS) registry number is 50-23-7.

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.

Tretinoin, a retinoid, is all-trans-retinoic acid formed from the oxidation of the aldehyde group of retinene to a carboxyl group. It occurs as yellow to light orange crystals or crystalline powder with a characteristic odor of ensilage. It is highly reactive to light and moisture. The chemical name for tretinoin is: (all-E)-3,7-dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2,4,6,8-nonatetraenoic acid. The molecular formula is $C_{20}H_{28}O_2$ and molecular weight is 300.44. Tretinoin has the following structural formula:

OLIVIA QUIDO FIRM & FADE I Cream contains Active: hydrocortisone 1% (10 mg),

hydroquinone 8% (80 mg), and tretinoin 0.1% (1 mg). Inactive: aloe barbadensis leaf powder, ascorbic acid, BHT, C13-14 isoparaffin, caprylic/capric triglyceride, cetyl alcohol, cyclopentasiloxane, diazolidinyl urea, dimethicone crosspolymer, dimethyl isosorbide, ethylhexyl stearate, glycerin, iodopropynyl butylcarbamate, kojic acid, laureth-7, maltodextrin, PEG/PPG-18/18 dimethicone, pentaclethra macroloba seed oil, phenoxyethanol, polyacrylamide, polyacrylate-13, polyisobutene, polysorbate 20, polysorbate 80, propylene glycol, purified water, sodium lauryl sulfate, stearyl alcohol, tocopherol, tocopheryl acetate, triethylene glycol, white petrolatum.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of the active ingredients in OLIVIA QUIDO FIRM & FADE I Cream 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

OLIVIA QUIDO FIRM & FADE I Cream is light yellow in color, and supplied in 28.35 g airless bottle, NDC 72864-562-01.

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 OLIVIA QUIDO FIRM & FADE I Cream as directed by the health care provider and do not use OLIVIA

QUIDO FIRM & FADE I Cream 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 OLIVIA QUIDO FIRM & FADE

I Cream. Because of the drying effect of this medication, a moisturizer may be applied to the face in the morning after washing.

Keep OLIVIA QUIDO FIRM & FADE I Cream 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,

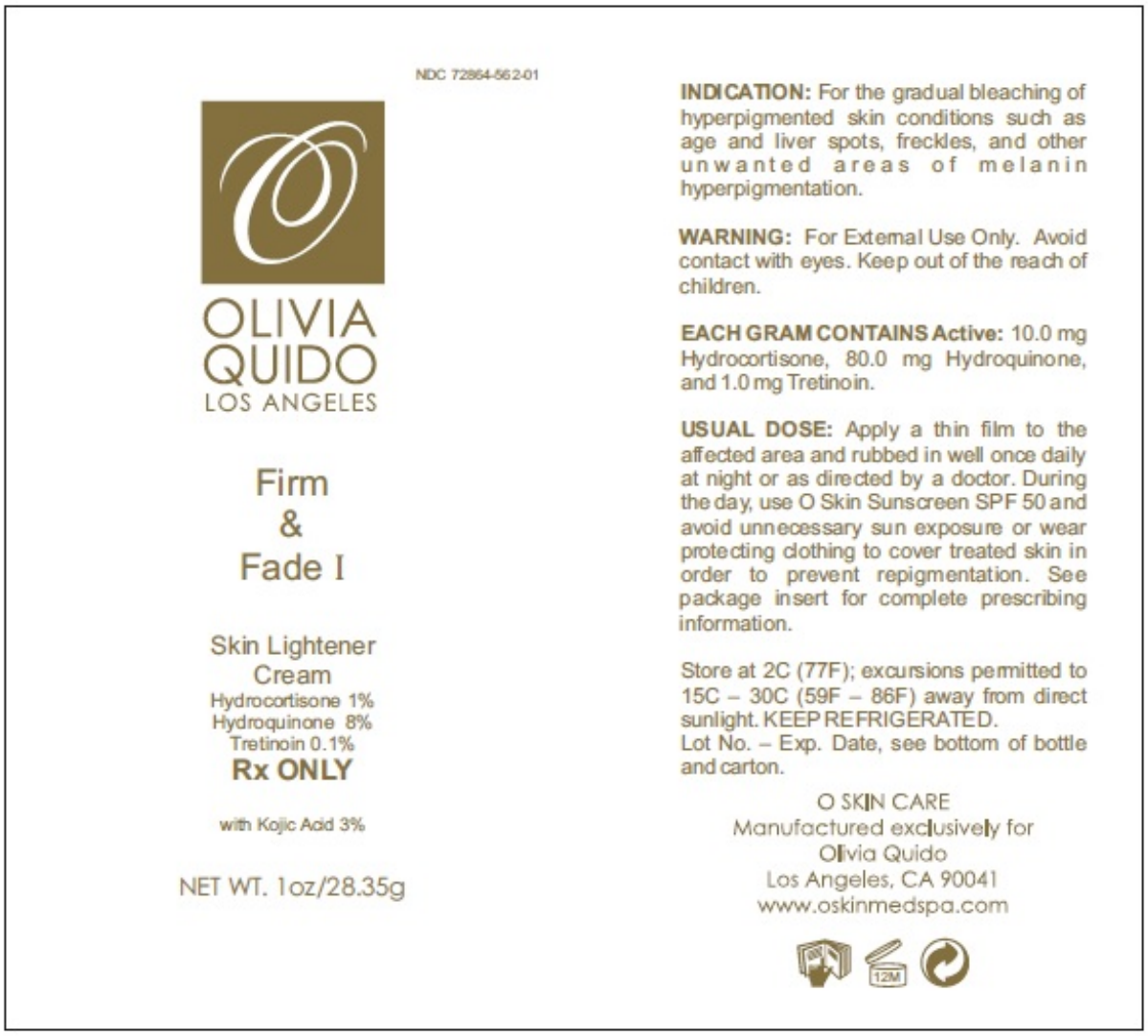
discontinue application of the medication and consult your health care provider. Seek medical attention if you

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 FIRM AND FADE I

hydrocortisone, hydroquinone, tretinoin cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72864-562
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	0.01 g in 1 g
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	0.08 g in 1 g
TRETINOIN (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R)	TRETINOIN	0.001 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
GLYCERIN (UNII: PDC6A3C0OX)	
CHLOROKOJIC ACID (UNII: UB7QQW2D47)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
PENTACLETHRA MACROLOBA SEED OIL (UNII: OM0BAV5397)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TRIETHYLENE GLYCOL (UNII: 3P5SU53360)	
PETROLATUM (UNII: 4T6H12BN9U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
LAURETH-7 (UNII: Z95S6G8201)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72864-562-01	1 in 1 BOX	09/09/2019	12/31/2022
1		28.35 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		09/09/2019	12/31/2024

Labeler - O Skin Pharmaceutical Corporation (081255426)

Revised: 3/2021 O Skin Pharmaceutical Corporation