

OBAGI C RX SYSTEM C CLARIFYING SERUM- hydroquinone solution
Obagi Cosmeceuticals 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.

OBAGI-C®
RX SYSTEM

WELCOME TO THE OBAGI-C® RX SYSTEM OF SKIN CARE PRODUCTS!

PATIENT INFORMATION

For Topical Use Only

Complete skin care regimen formulated with 4% hydroquinone to reduce hyperpigmentation and other essential ingredients to help address the signs of skin aging caused by photoaging.

Please read this product information prior to use of the Obagi-C® Rx System. Any questions regarding your particular skin care regimen should be directed to your physician. More information about the Obagi-C® Rx System or other Obagi systems is available at our website at www.obagi.com.

PHYSICIAN PRESCRIBING INFORMATION

Rx only

FOR EXTERNAL USE ONLY

62032-106-10 Obagi-C® Rx System C-Clarifying Serum for Normal to Dry Skin

Each gram of Obagi-C® Rx System C-Clarifying Serum for Normal to Dry Skin contains:

Active: Hydroquinone, USP 4% (40 mg per g)

Inactives: ascorbic acid, propylene carbonate, propylene glycol, sodium lauryl sulfate, water

62032-122-10 Obagi-C® Rx System C-Clarifying Serum for Normal to Oily Skin

Each gram of Obagi-C® Rx System C-Clarifying Serum for Normal to Oily Skin contains:

Active: Hydroquinone, USP 4% (40 mg per g)

Inactives: ascorbic acid, dipropylene glycol, fragrance, propylene carbonate, propylene glycol, SD alcohol-39-C, sodium lauryl sulfate, water

62032-105-36 Obagi-C® Rx System C-Therapy Night Cream

Each gram of Obagi-C® Rx System C-Therapy Night Cream contains:

Active: Hydroquinone, USP 4% (40 mg per g)

Inactives: ascorbic acid, BHT, cetyl alcohol, disodium EDTA, glycerin, lactic acid, methylparaben, phenyl trimethicone, PPG-2 myristyl ether propionate, propylparaben, saponins, sodium lauryl sulfate, sodium metabisulfite, TEA-salicylate, tocopheryl acetate, water

Description

Hydroquinone is 1,4-benzenediol. Hydroquinone occurs as fine, white needles. The drug is freely soluble in water and in alcohol. Chemically, hydroquinone is designated as p-dihydroxybenzene; the empirical formula is $C_6H_6O_2$; molecular weight is 110.11 g per mol.

The chemical structure is in the diagram.



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) and suppression of other melanocyte metabolic processes. Exposure to sunlight or ultraviolet light will cause repigmentation of the bleached areas, which may be prevented by the use of sunscreen agents contained in the Obagi-C® Rx System Sun Shield Matte Broad Spectrum SPF 50.

INDICATIONS AND USAGE

The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentigines, and other unwanted areas of melanin hyperpigmentation.

DOSAGE AND ADMINISTRATION

A thin application should be applied once or twice daily or as directed by a physician. If no improvement is seen after three (3) months of treatment, use of this product should be discontinued. Sun exposure should be limited by using a sunscreen agent or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

WARNINGS

- 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 product.
- Test for skin sensitivity before using by applying a small amount to an unbroken patch of skin and check within 24 hours. Minor redness is not a contraindication, but where there is itching or vesicle formation or excessive inflammatory response, the product should be discontinued and a physician consulted. Close patient supervision is recommended.

- Avoid contact with eyes, nose, mouth, and lips. In case of accidental contact, the patient should rinse thoroughly with water and contact a physician.
- Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity.

The Obagi-C® Rx System C-Therapy Night Cream 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 nonasthmatic people.

PRECAUTIONS

(See WARNINGS.)

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.

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with topical hydroquinone. It is also not known whether hydroquinone can cause fetal harm when used topically on a pregnant woman or affect reproductive capacity. It is not known to what degree, if any, topical hydroquinone is absorbed systemically. Topical hydroquinone should be used on pregnant women only when clearly indicated.

Nursing Mothers

It is not known whether topical hydroquinone is absorbed or excreted in human milk. Caution is advised when topical hydroquinone is used by a nursing mother.

Pediatric Usage

Safety and effectiveness in children, below the age of 12 years, have not been established.

ADVERSE REACTIONS

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

To report SUSPECTED ADVERSE REACTIONS, contact Obagi Medical Products, a division of Valeant Pharmaceuticals North America LLC, at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

CONTRAINDICATIONS

People with prior history of sensitivity or allergic reaction to this product or any of its ingredients should not use it. The safety of topical hydroquinone use during pregnancy or in children (12 years and under) has not been established.

HOW SUPPLIED

Obagi-C® Rx System C-Clarifying Serum

(Hydroquinone, USP 4%) for Normal to Dry Skin is available as follows:

1 fl. oz. (30 mL) bottle

NDC 62032-106-10

Obagi-C[®] Rx System C-Clarifying Serum

(Hydroquinone, USP 4%) for Normal to Oily Skin is available as follows:

1 fl. oz. (30 mL) bottle

NDC 62032-122-10

Obagi-C[®] Rx System C-Therapy Night Cream

(Hydroquinone, USP 4%) is available as follows:

Net wt. 2 oz. (57 g) bottle

NDC 62032-105-36

Store at controlled room temperature: 15° to 25°C (59° to 77°F). Keep out of direct sunlight.

Distributed by:

Obagi Medical Products, Inc., a division of Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA

U.S. Patent 6,299,889

Obagi-C is a trademark of Valeant Pharmaceuticals International, Inc. or its affiliates.

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PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

OBAGI-C[®]

RX SYSTEM

NDC# 62032-106-10

C-CLARIFYING SERUM

SKIN LIGHTENING SERUM

WITH VITAMIN C 10%

HYDROQUINONE USP, 4%

RX ONLY

FOR NORMAL TO DRY SKIN

AM

1fl. oz. (30 mL)

|O|B|A|G|I|-C[®]
RX SYSTEM
NDC# 62032-106-10

C-CLARIFYING SERUM

SKIN LIGHTENING SERUM
WITH VITAMIN C 10%
HYDROQUINONE USP, 4%
RX ONLY

FOR NORMAL TO DRY SKIN

AM

1 fl. oz. (30 mL)

C-Clarifying Serum contains the antioxidant Vitamin C and prescription-strength hydroquinone. This patented formulation for normal to dry skin reduces the appearance of dark spots for a lighter, brighter complexion.

Dosage and administration: Use once daily in the morning. Apply 5 to 7 drops to the entire face or as directed by your skin care physician. Massage in gently.

Indications and usage: The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentiginos, and other unwanted areas of melanin hyperpigmentation.

Each gram of Obagi-C® Rx System C-Clarifying Serum for Normal to Dry Skin contains:

Active ingredient: Hydroquinone USP, 4% (40 mg/g)

Inactive ingredients: propylene glycol, water (aqua), ascorbic acid, propylene carbonate, sodium lauryl sulfate

See enclosed Package Insert for full prescribing information. Store at controlled room temperature: 15°C–25°C (59°F–77°F). Keep out of direct sunlight.

OBAGI
MEDICAL

 Recyclable

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

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Made in USA with U.S. and Imported components 9418602



OBAGI C RX SYSTEM C CLARIFYING SERUM

hydroquinone solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62032-106
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 mL

Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-106-10	1 in 1 CARTON	01/01/2010	
1		30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/2010	

Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
G.S. COSMECEUTICAL USA, INC.		017014734	MANUFACTURE(62032-106)

Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-106) , LABEL(62032-106) , PACK(62032-106)

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Obagi Cosmeceuticals LLC