

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

### Patient information—For topical use only

Help correct early signs of aging and skin damage before they become a problem! This early intervention system helps keep your skin protected and proactively addresses emerging signs of skin damage to refresh and maintain youthful, healthy-looking skin. The Obagi-C Rx System is a unique skin care regimen that combines the benefits of both prescription-strength hydroquinone and the power of Vitamin C.

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](http://www.obagi.com).

### Physician prescribing information—For external use only—Rx 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 ingredient:** Hydroquinone USP, 4% (40 mg/g)

**Inactive ingredients:** propylene glycol, water, ascorbic acid, propylene carbonate, sodium lauryl sulfate

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

**Inactive ingredients:** water, propylene glycol, alcohol denat., dipropylene glycol, ascorbic acid, propylene carbonate, sodium lauryl sulfate, fragrance

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

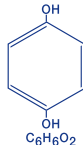
Each gram of Obagi-C Rx System C-Therapy Night Cream contains:

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

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

### 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/mol. The chemical structure is in diagram to right.



### 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 sunblocking agents or 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, a sunblocking 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, product should be discontinued and physician consulted. Close patient supervision is recommended.
- Avoid contact with eyes, nose, mouth, and lips. In case of accidental contact, 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 (also 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 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 a physician notified immediately.

### 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

- The 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
- The 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
- The 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°C–25°C (59°F–77°F). Keep out of direct sunlight.

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