

OBAGI-C RX SYSTEM C-THERAPY SKIN LIGHTENING WITH VITAMINS C AND E - hydroquinone cream
OMP, INC.

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

**PATIENT INFORMATION
FOR TOPICAL USE ONLY**

With Obagi-C Rx, you're on your way to healthier, refreshed, revitalized skin from cell to surface. Obagi-C Rx Systems promote skin rejuvenation from the inside out using a formulation of prescription-strength hydroquinone USP, 4%, which reduces the appearance of hyperpigmentation and age spots, combined with 10% L-ascorbic acid (Vitamin C)—the only topical antioxidant proven to stimulate collagen synthesis and protect your skin by minimizing future skin cell damage.

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 toward your physician or skin care specialist. You can also obtain more information about the Obagi-C Rx System or other Obagi systems by visiting our Web site at 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

ACTIVE INGREDIENT

Hydroquinone USP, 4%

INACTIVE INGREDIENTS

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

ACTIVE INGREDIENT

Hydroquinone USP, 4%

INACTIVE INGREDIENTS

Ascorbic Acid, Dipropylene Glycol, Ethyl Alcohol, Fragrance, Propylene Carbonate, Propylene Glycol, Sodium Lauryl Sulfate, Water

62032-105-36 OBAGI-C RX SYSTEM C-THERAPY NIGHT CREAM

ACTIVE INGREDIENT

Hydroquinone USP, 4%

INACTIVE INGREDIENTS

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 C₆H₆O₂; 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 C-SunGuard SPF 30.

INDICATIONS AND USAGE

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

DOSAGE AND ADMINISTRATION

A thin application should be applied to the affected area twice daily or as directed by a physician. If no improvement is seen after 8-12 weeks 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 repigmentation.

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 medication.
- 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, or lips. In case of accidental contact, patient should rinse eyes, nose, mouth, or lips with water and contact 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 serious allergic-type reactions (e.g., hives, itching, wheezing, anaphylaxis, severe asthma attacks) in certain susceptible persons.**

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 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: 2 oz. (57 g) bottle NDC 62032-105-36

Store at controlled room temperature: 15°-25°C (59°-77°F), and keep out of direct sunlight.

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PRINCIPAL DISPLAY PANEL - 57 G BOTTLE CARTON
OBAGI-C™
RX SYSTEM
NDC# 62032-105-36
C-THERAPY
NIGHT CREAM
SKIN LIGHTENING CREAM
WITH VITAMINS C & E
HYDROQUINONE USP, 4%
RX ONLY
PM
NET WT. 2 OZ. (57g)

