

OBAGI - C - hydroquinone liquid
YS PLUS 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.

Drug Facts

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

For external use only

Rx only

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.

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

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

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

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.

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of 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.

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

A thin application should be applied once or twice daily or as directed by a physician. no improvement is seen after three (3) months of treatment, use of this product should be discontinued. Sun exposure may 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.

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 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.

(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. 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.

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.

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

1 7/8"

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.

OBAGI-C[®]
RX SYSTEM
NDC# 62032-106-10

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, 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-C is a registered trademark of OMP, Inc.
Patent #6,299,899

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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)



6"

OBAGI - C

hydroquinone liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69269-106
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69269-106-10	1 in 1 CARTON		
1		30 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/01/2014	

Labeler - YS PLUS CORPORATION (843007597)

Establishment

Name	Address	ID/FEI	Business Operations
YS PLUS CORPORATION		843007597	repack(69269-106)

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