

Obagi® Nu-Derm® Clear (Hydroquinone USP, 4%) Skin Bleaching Cream
Obagi Nu-Derm Blender® (Hydroquinone USP, 4%) Skin Bleaching Cream
Obagi Nu-Derm Sunfader® (Hydroquinone USP, 4%; Octinoxate USP, 7.5%;
Oxybenzone USP, 5.5%) Skin Bleaching Cream with Sunscreens

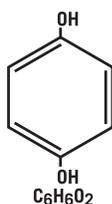


Rx Only

FOR EXTERNAL USE ONLY

DESCRIPTION:

Hydroquinone is 1, 4-benzenediol. The drug is freely soluble in water and in alcohol. Chemically, hydroquinone is designed as p-dihydroxybenzene; the empirical formula is $C_6H_6O_2$; molecular weight is 110.11 g/mol. The chemical structure is in the diagram below.



Each gram of Obagi Nu-Derm Clear contains Hydroquinone USP 40 mg/gm in a base of purified water, cetyl alcohol, glycerin, sodium lauryl sulfate, stearyl alcohol, tocopheryl acetate, ascorbic acid, sodium metabisulfite, lactic acid, saponins, disodium EDTA, methylparaben, BHT, propylparaben, and butylparaben.

Each gram of Obagi Nu-Derm Blender contains Hydroquinone USP 40 mg/gm in a base of purified 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, saponins, disodium EDTA, BHT, and propylparaben.

Each gram of Obagi Nu-Derm Sunfader contains Hydroquinone USP 40 mg/gm, Octinoxate USP, 7.5% and Oxybenzone USP, 5.5% in a base of purified water, cetyl alcohol, glycerin, sodium lauryl sulfate, stearyl alcohol, tocopheryl acetate, ascorbic acid, sodium metabisulfite, disodium EDTA, methylparaben, saponins, propylparaben, BHT, and butylparaben.

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 Obagi Nu-Derm Sunfader.

INDICATIONS AND USAGE:

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

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.

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, 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.

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 the physician notified immediately.

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.

HOW SUPPLIED:

Obagi Nu-Derm Clear is available as follows:

2 oz. (57 gm) bottle
NDC 62032-101-36

Obagi Nu-Derm Blender is available as follows:

2 oz. (57 gm) bottle
NDC 62032-100-36
1 oz. (28.5 gm) bottle
NDC 62032-100-10

Obagi Nu-Derm Sunfader is available as follows:

2 oz. (57 gm) bottle
NDC 62032-116-36

Store at 15°C-25°C
(59°F-77°F).

30700310X Rev. 07/10

OMP, Inc. Long Beach, CA 90806 USA 1-800-636-7546