

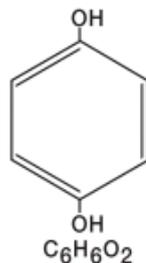
Obagi Nu-Derm® Clear
Hydroquinone USP, 4% (40 mg/g)
Skin Bleaching Cream

Obagi Nu-Derm Blender®
Hydroquinone USP, 4% (40 mg/g)
Skin Bleaching Cream

Rx Only
FOR EXTERNAL USE ONLY

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 110.0.



Each gram of Obagi Nu-Derm Clear contains:

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

Inactive ingredients: 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:

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

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 sun-blocking agents or sunscreen agents contained in Obagi Sun Shield Matte Broad Spectrum SPF 50.

Indications and Usage:

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

Contraindications:

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

Warnings:

Caution: 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 in 24 hours. Minor redness is not a contraindication, but where there is itching or vesicle formation or excessive inflammatory response, further treatment is not advised. 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.

Warnings:

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 medication should be discontinued and the physician notified immediately.

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 sun-blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

How Supplied:

Obagi Nu-Derm Blender is available as follows:
Net wt. 2 oz. (57 g) bottle NDC 62032-100-36
Net wt. 1 oz. (28 g) bottle NDC 62032-100-10

Obagi Nu-Derm Clear is available as follows:
Net wt. 2.0 oz. (57 g) tube NDC 63032-101-36

Store at controlled room temperature:
15°C-25°C (59°F-77°F).



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Long Beach, CA 90806

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