

PHYSICIAN PRESCRIBING INFORMATION

Obagi Nu-Derm System

Obagi Nu-Derm Clear™

(Hydroquinone USP, 4%) Skin Bleaching Cream

Obagi Nu-Derm Blender™

(Hydroquinone USP, 4%) Skin Bleaching Cream

Obagi Nu-Derm Sunfader™

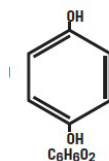
(Hydroquinone USP, 4%; Octinoxate USP, 7.5%; Oxybenzone USP, 5.5%) Skin Bleaching Cream with Sunscreens

Rx Only

FOR EXTERNAL USE ONLY

DESCRIPTION

Hydroquinone is 1,4-benzenediol. 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 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 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 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

The gradual bleaching of hyperpigmented skin conditions

such as chloasma, melasma, freckles, senile lentiginos, and other unwanted areas of melanin hyperpigmentation. Obagi Nu-Derm Sunfader is intended for daytime use as it contains sunscreen agents.

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 that 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 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. In case of accidental contact, patient should rinse eyes thoroughly with water and contact physician. A bitter taste and anesthetic effect may occur if applied to lips.

Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity. Obagi Sunfader is formulated for use as a skin bleaching agent and should not be used for the prevention of sunburn.

Warning: 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 (SEE WARNINGS)

General. 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 that 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 to the affected area 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 repigmentation.

HOW SUPPLIED

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 Clear is available as follows:
2 oz. (57 gm) bottle NDC 62032-101-36
1 oz. (28.5 gm) bottle NDC 62032-101-10

Obagi Nu-Derm Sunfader is available as follows:
2 oz. (57 gm) bottle NDC 62032-116-36

Store at 25 C (77 F); excursion permitted to 15 C–30 C (59 F–86 F).

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