

Hydroquinone Q&A

Recently, there has been renewed interest in hydroquinone, an active ingredient in several Obagi products. The media and resulting patient interest is related to a U.S. Food and Drug Administration (FDA) regulatory action that addresses and affects *over-the-counter* products containing hydroquinone. It is important to note that prescription based hydroquinone products, including Nu-Derm products, remain safe and effective for patient use. Obagi Medical Products agrees that 4% hydroquinone should not be available without physician supervision and should remain subject to prescription use only.

Are Obagi products safe?

Hydroquinone has been an active ingredient in many topical drug products marketed in the U.S. for more than 40 years without safety incident. Obagi Medical Products has sold hydroquinone for almost 25 years, over which time millions of units have been administered without safety issues.

4% Hydroquinone, the active ingredient in Nu-Derm Clear, Blender, Sunfader and Obagi-C Rx, has previously been approved for combination use in the treatment of melasma (dark spots (hyperpigmentation) on facial skin) by the FDA.

What data is available to support that 4% HQ is safe when used under physician care?

There is ample documented safety data and evidence available to support the use of hydroquinone in topical prescription drugs. In addition to its 40 plus year history of widespread global commercial marketing this includes published scientific literature such as the following selections:

- Large epidemiological studies on workers exposed to hydroquinone over many years confirm hydroquinone's lack of carcinogenicity in humans. In-depth surveys of 9000 workers involved in the manufacture of hydroquinone who had

prolonged exposure to high concentrations of hydroquinone have demonstrated lower premature death rates and reduced cancer rates in exposed workers compared to nonexposed controls. (DeCaprio AP. The toxicology of hydroquinone - relevance to occupational and environmental exposure. *Crit Rev Toxicol* 1999; 29 (3): 283-330.)

- Hydroquinone is a ubiquitous chemical to which most humans are exposed in their daily lives. Hydroquinone and arbutin (hydrolyzed to hydroquinone by the acidic milieu of the stomach) are found in many common foods such as cranberries, blueberries, pears, beans, all-wheat breads and cereals, tea, coffee, red wine, beer, broccoli, and onions. Background levels of hydroquinone are found in the blood and urine of all individuals, even those on low-hydroquinone diets. (Deisinger PJ, Hill TS, English JC. Human exposure to naturally occurring hydroquinone. *J Toxicol Environ Health* 1996; 47 (1): 31-46.)
- Howard I. Maibach, M.D., professor of dermatology at the University of California School of Medicine, San Francisco, and expert in the field, summarizes the safety profile of hydroquinone as follows: "Overall, adverse events reported with the use of hydroquinone ... have been relatively few and minor in nature ... hydroquinone is undoubtedly the most active and safest skindepigmenting substance". *Journal of Toxicology and Environmental Health*, 1998, pages 301- 317.



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- Dr. Pearl Grimes, Director of the Vitiligo and Pigmentation Institute of Southern California recently noted in a letter to the editor of the Journal of Cosmetic Dermatology that "Trials of topical hydroquinone treatments have provided substantial data on the efficacy and safety of this treatment, extending over 40 years of use. The reported adverse effects of topically applied hydroquinone are all minor such as skin irritation, hyper- and hypo-pigmentation, ochronosis and nail discoloration. Importantly, no cases of carcinogenesis have been reported in over 40 years of the clinical use of topical hydroquinone." Dr. Grimes also restated the need for effective treatment of pigmentation disorders: "Pigment disorders, while not life threatening, can have a significant psychological impact on those who are disfigured by multicolored skin. Hydroquinone has long been regarded by dermatologists as the gold standard in the treatment of certain pigmentary disorders of the skin. It is an effective treatment that provides improvements in both appearance and quality of life." with the use of hydroquinone ... have been relatively few and minor in nature ... hydroquinone is undoubtedly the most active and safest skidepigmenting substance". *Journal of Toxicology and Environmental Health, 1998, pages 301- 317.*

Can using your products cause cancer?

There is no evidence in human clinical studies to suggest that hydroquinone could cause cancer. However, the absence of modern carcinogenicity studies to support prolonged human use as a topical drug has led to FDA concern for unmonitored over-the-counter use of hydroquinone products. Prescription drug products, on the other hand, permit frequent physician oversight to ensure that the product is being used appropriately and safely..

What are the chances that my patients will get Ochronosis?

Published scientific literature supports that the occurrence of ochronosis (a gradual blueblack darkening of the skin) appears to be related to the use of significantly higher concentrations and/or unregulated foreign formulations of hydroquinone. *Critical Reviews in Toxicology, May 1999, pages 283-330.* Patients should always report any unwanted changes in skin color to their physician.

Have your products ever caused ochronosis or cancer in patients?

Obagi Medical Products has never received a report of cancer or ochronosis related to use of our products.

Regarding the Recent FDA Communications Regarding OTC Skin Bleaching?

It has been a core OMP operating principle that HQ products should be provided from physicians to their patients with the highest possible standards in manufacturing, quality assurance, and physician, staff and patient training and education. As such, we are encouraged to see the FDA take a stronger stance in monitoring and controlling the use of OTC and other skin changing ingredients in the OTC channel. We believe that Hydroquinone is a highly effective drug ingredient that should only be provided to the public under physician supervision and care.