

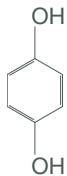


Remergent™ HQ
[Hydroquinone USP 4%]
Intense Bleaching Cream

I. DESCRIPTION.

Remergent™ HQ contains hydroquinone USP 4% and patented liposomes (microscopic vesicles in the nanometer range, made up of lipid bilayers).¹ Hydroquinone is 1,4-benzenediol. Hydroquinone is structurally related to monobenzene. Hydroquinone occurs as fine white needles. The drug is freely soluble in water and in alcohol and has a pK_a of 9.96. Chemically, hydroquinone is designated as p-dihydroxybenzene; the empirical formula is $C_6H_6O_2$; the molecular weight is 110.1.

The structural formula is



Rx only.
FOR TOPICAL USE ONLY

ACTIVE INGREDIENT

Hydroquinone USP 4%

INACTIVE INGREDIENTS

Water, cyclopentasiloxane, cyclomethicone, glycerin, dimethicone, PEG/PPG-18/18 dimethicone, arabinoside extract, butylene glycol, caprylyl glycol, disodium EDTA, L-ergothioneine, ethylhexylglycerin, evodia rutaecarpa fruit extract, hexylene glycol, lecithin, micrococcus lysate, 1,2-octanediol, phenoxyethanol, polysorbate 80, sodium metabisulfite, sorbic acid.

II. CLINICAL PHARMACOLOGY

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of tyrosine to 3-(3,4-dihydroxyphenyl)alanine (dopa)² and suppression of other melanocyte metabolic processes.³ Exposure to sunlight or ultraviolet light will cause repigmentation of the bleached areas.⁴

III. INDICATIONS AND USAGE

Remergent™ HQ is indicated for the gradual treatment of ultraviolet-induced dyschromia, including photo-aging, solar and senile lentigenes, as well as discoloration resulting from the use of oral contraceptives, pregnancy, hormone replacement therapy, or skin trauma.

IV. CONTRAINDICATIONS

Remergent™ HQ is contraindicated in any patient with a prior history of hypersensitivity or allergic reaction to hydroquinone or any of the other ingredients. The safety of topical hydroquinone use during pregnancy or on children (12 years and under) has not been established.

V. WARNINGS

A. Caution: Hydroquinone is a depigmenting 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.

B. Test for skin sensitivity before using Remergent™ HQ 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, vesicle formation, or excessive inflammatory response, further treatment is not advised. Close patient supervision is recommended. Contact with the eyes should be avoided. If no lightening effect is noted after 2 months of treatment, use of Remergent™ HQ should be discontinued.

C. Sunscreen use is an essential aspect of hydroquinone therapy, because even minimal sunlight sustains melanocytic activity. To prevent repigmentation during treatment and maintenance therapy, sun exposure on treated skin should be avoided by application of a broad spectrum sunscreen (SPF 15 or greater) or by use of protective clothing.

D. Keep this and all medications out of reach of children. In case of accidental ingestion, contact a physician or a poison control center immediately.

E. Warning: Contains sodium metabisulfite, a sulfite that may cause serious allergic reactions (e.g., hives, itching, wheezing, anaphylaxis, severe asthma attack) in certain susceptible persons.

F. On rare occasions, a gradual blue-black darkening of the skin may occur, in which case, use of Remergent™ HQ should be discontinued and a physician contacted immediately.

G. Avoid using other topical products on the same area at the same time unless directed to do so by your doctor. Use caution and talk to your doctor before using hydroquinone topical if you are also using medicated or abrasive soaps or cleansers, and other topical products with a strong drying effect on the skin, products with high concentrations of alcohol, astringents, spices or lime, or other preparations or processes that may dry or irritate the skin.

VI. PRECAUTIONS (SEE WARNINGS)

A. 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 can affect reproductive capacity. It is not known to what

degree, if any, topical hydroquinone is absorbed systemically. Topical hydroquinone should be used in pregnant women only if clearly needed.

B. Nursing mothers: It is not known whether topical hydroquinone is absorbed or excreted in human milk. Because many drugs are excreted in human milk, caution is advised when hydroquinone is used by a nursing mother.

C. Pediatric usage: Safety and effectiveness in pediatric patients below the age of 12 years have not been established.

D. Geriatric Usage: Clinical studies of hydroquinone did not include sufficient numbers of subjects, aged 65 and over, to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range reflecting the greater frequency of decreased hepatic, renal or cardiac functions and concomitant disease or other drug therapy.

VII. ADVERSE REACTIONS

A. No systemic reactions have been reported. Occasional cutaneous hypersensitivity (localized contact dermatitis) may occur, in which case the medication should be discontinued and the physician notified immediately.

B. On rare occasions, a gradual blue-black darkening of the skin may occur, in which case, use of Remergent™ HQ should be discontinued and a physician contacted immediately.

VIII. OVERDOSAGE

There have been no systemic reactions reported from the use of topical hydroquinone. However, 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.

IX. DOSAGE AND ADMINISTRATION

Remergent™ HQ should be applied to the affected areas twice daily, morning and before bedtime, or as

directed by a physician. To prevent re-pigmentation during and after the use of Remergent™ HQ, sun exposure should be limited and a sunscreen agent or sun-protective clothing should be used to cover the treated areas. There is no recommended dosage for pediatric patients under 12 years of age except under the advice and supervision of a physician.

X. HOW SUPPLIED

Remergent™ HQ is supplied as a cream. Size: 30 mL airless bottle with metered-dose dispenser pump. Store at controlled temperature 59° -77°F (15°-25°C). DO NOT FREEZE.

REFERENCES

1. Yarosh, D. Liposomes in Investigative Dermatology. Photodermatol. Photoimmunol Photomed 17:203-212, 2001
2. Denton C, Fitzpatrick TB, Lerner AB. Inhibition of Melanin Formation by Chemical Agents. J Invest Dermatol 18:119-135, 1952
3. Fitzpatrick T.B., Jimbow K., Obata M., Panthak M. Mechanism of Depigmentation by Hydroquinone. J Invest Dermatol 62:436-449, 1974
4. Anderson R.R., Parish J.A., Pitts, D., Urbach, F. UV - A: Biological Effects of Ultraviolet Radiation with Emphasis on Human Responses to Longwave Ultraviolet. New York and London 151, 1978

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