

# EpiQuin<sup>®</sup> Micro

(hydroquinone USP 4%)

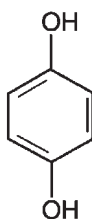
Skin Lightening Moisturizing Topical Cream

**Rx only.**

**FOR EXTERNAL USE ONLY.**

## I. DESCRIPTION

EpiQuin<sup>®</sup> Micro contains hydroquinone USP 4% and retinol (vitamin A) incorporated into patented porous microspheres (Microsponge<sup>®\*</sup> System) composed of methyl methacrylate/glycol dimethacrylate crosspolymer. This polymeric system has been shown to provide gradual release of active ingredient into the skin.<sup>1</sup> 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<sub>a</sub> of 9.96. Chemically, hydroquinone is designated as p-dihydroxybenzene; the empirical formula is C<sub>6</sub>H<sub>6</sub>O<sub>2</sub>; the molecular weight is 110.1. The structural formula is:



### ACTIVE INGREDIENT:

Hydroquinone USP 4%

### OTHER INGREDIENTS:

Water, Caprylic/Capric Triglyceride, Emulsifying Wax, Dimethicone, Glycerin, C10-30 Cholesterol/Lanosterol Esters, Cetyl Alcohol, Cetyl Ricinoleate, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer, Retinol (Vitamin A), Tocopheryl Acetate (Vitamin E), Ascorbic Acid (Vitamin C), Ascorbyl Palmitate, Bisabolol, Cyclomethicone, PEG-10 Soy Sterol, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Magnesium Aluminum Silicate, TEA-Stearate, Cetyl Phosphate, Butylated Hydroxy Toluene, Propyl Gallate, Disodium EDTA, Benzyl Alcohol, Methylparaben, Phenoxyethanol, Polysorbate 20, Triethanolamine, Sodium Metabisulfite.

## 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)<sup>2</sup> and suppression of other melanocyte metabolic processes.<sup>3</sup> Exposure to sunlight or ultraviolet light will cause repigmentation of the bleached areas.<sup>4</sup>

## III. INDICATIONS AND USAGE:

EpiQuin<sup>®</sup> Micro is indicated for the gradual treatment of ultraviolet-induced dyschromia and discoloration resulting from the use of oral contraceptives, pregnancy, hormone replacement therapy, or skin trauma.

## IV. CONTRAINDICATIONS:

EpiQuin<sup>®</sup> Micro 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 EpiQuin<sup>®</sup> Micro 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 two months of treatment, use of EpiQuin<sup>®</sup> Micro 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 EpiQuin<sup>®</sup> Micro should be discontinued and a physician contacted immediately.

#### **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 when clearly indicated.

B. **Nursing mothers:** It is not known whether topical hydroquinone is absorbed or 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.

#### **VII. ADVERSE REACTIONS:**

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.

#### **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:**

EpiQuin<sup>®</sup> Micro should be applied to the affected areas twice daily, morning and before bedtime, or as directed by a physician.

Promptly tighten cap after each use. To prevent repigmentation during and after the use of EpiQuin<sup>®</sup> Micro, 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:**

EpiQuin<sup>®</sup> Micro is supplied as follows:

SIZE: 1 oz tube (30 g)

NDC NUMBER: 67402-010-30

Store at 25°C (77°F); excursions permitted to 15°–30°C (59°–86°F) (see USP Controlled Room Temperature)

#### **REFERENCES**

1. Leyden J, Maibach H, Melendrez J, Nacht S, Patel R, Wester RC. Controlled release of benzoyl peroxide from a porous microspore polymeric system can reduce topical irritancy. *J of the American Academy of Dermatology*. 1991;24:720–726.
2. Denton C, Fitzpatrick TB, Lerner AB. Inhibition of melanin formation by chemical agents. *J Invest Dermatol*. 1952;18:119–135.
3. Fitzpatrick TB, Jimbow K, Obata M, Panthak M. Mechanism of depigmentation by hydroquinone. *J Invest Dermatol*. 1974;62:436–449.
4. Anderson RR, Parrish JA, Pitts D, Urbach F. UVA, *Biological Effects of Ultraviolet Radiation with Emphasis on Human Responses to Longwave Ultraviolet*. New York and London: Plenum Press;1978:151.

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