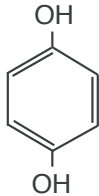


Aclaro PD® (hydroquinone USP 4%) bioadhesive emulsion

Rx Only • For Topical Use Only

Description: 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 with a pKa of 9.96. Chemically, hydroquinone is designated as p-dihydroxybenzene; the empirical formula is C₆H₆O₂; molecular weight 110.1. The structural formula is:



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ACTIVE INGREDIENT: hydroquinone USP 4%.

Other Ingredients: ascorbic acid, benzyl alcohol, butyl methoxydibenzoyl-methane, C12-15 alkyl benzoate, cetearyl ethylhexanoate, cetyl alcohol, cetyl esters, cetyl palmitate, DEA-cetyl phosphate, dimethicone, dimethylacrylamide/acrylic acid/polystyrene ethyl methacrylate copolymer, disodium EDTA, ethylhexyl methoxycinnamate, glycerin, glycolic acid, hydroxyethylcellulose, phenoxyethanol, propylene glycol (and) glyceryl oleate (and) BHA (and) propyl gallate (and) citric acid, purified water, stearic acid.

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)¹ and suppression of other melanocyte metabolic processes.²

Indications and Usage: Aclaro PD® 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.

Contraindications: Aclaro PD® is contraindicated in any patient that has 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.

Warnings:

A. Caution: Hydroquinone is a depigmenting 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 medication.

B. Test for skin sensitivity before using Aclaro PD® (hydroquinone USP 4%) bioadhesive emulsion 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 Aclaro PD® bioadhesive emulsion should be discontinued.

C. Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocyte activity. The sunscreens in Aclaro PD® bioadhesive emulsion provide the necessary sun protection during therapy. During and after the use of Aclaro PD® bioadhesive emulsion, sun exposure should be limited or sun-protective clothing should be used to cover the treated areas to prevent repigmentation.

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

E. On rare occasions, a gradual blue-black darkening of the skin may occur. If this occurs, the product should be discontinued and a physician contacted immediately.

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 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.

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.

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 which does not preclude treatment.

Dosage and Administration: Aclaro PD® bioadhesive emulsion should be applied to the affected areas twice daily, or as directed by a physician. There is no recommended dosage for pediatric patients under 12 years of age except under the advice and supervision of a physician.

How Supplied:

Aclaro PD® (hydroquinone USP 4%) bioadhesive emulsion is available in a:

1.5 ounce airless pump bottle
NDC 68712-015-02

Store at controlled room temperature: 15°-30° C (59°-86° F)

References:

- Denton C., Lerner A.B., and Fitzpatrick T.B. "Inhibition of Melanin Formation by Chemical Agents." *Journal of Investigative Dermatology*. 1952;18:119-135.
- Jimbow K., Obata H., Pathak M., and Fitzpatrick T.B. "Mechanism of Depigmentation by Hydroquinone." *Journal of Investigative Dermatology*. 1974;62:436-449.

Manufactured for:
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U.S. Pat. No.: 5,942,243

July 2008