HYDRO-Q- hydroquinone gel
Dermavance Pharmaceuticals

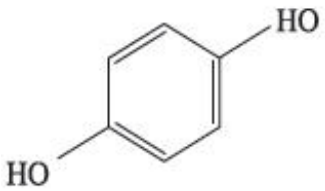
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

HYDRO-Q® (Hydroquinone 4%) Gel

RX Only

FOR EXTERNAL USE ONLY

HYDRO-Q® contains hydroquinone USP 4%. Hydroquinone is 1, 4-Benzenediol {CAS 123-31-91}. Hydroquinone is structurally related to monobenzone. Hydroquinone occurs as fine white needles. The drug is freely soluble in water and in alcohol and has a pKa of 9.96. Chemically, hydroquinone is designated as p-dihydroxybenzene; the empirical formula is C6H6O2; The molecular weight is 110.1. The structural formula is:



ACTIVE INGREDIENT

Hydroquinone USP 4%

OTHER INGREDIENTS: Purified water, Carbomer 940, Sodium Metabisulfite, Sodium Hydroxide, Methylparaben, Edetate Disodium.

CLINICAL PHARMACOLOGY

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic hydroquinone. oxidation of tyrosine to 3, 4-dihydroxyphenylalanine (dopa) 1 and suppression of other melanocyte metabolic processes. Exposure to sunlight or ultraviolet light will cause regimentation of the bleached areas.

INDICATIONS AND USAGE

HYDRO-Q® is indicated for the gradual bleaching of hyperpigmented skin conditions such as chlosma, melasma, freckles, senile lentigines and areas of melanin hyperpigmentation.

CONTRAINDICATIONS

HYDRO-Q® is contraindicated in any patient that has a prior history of sensitivity or allergic reaction to hydroquinone or any of the other ingredients. The safety of topical hydroquinone use during pregnancy or in children (12 years and under) has not been established.

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 HYDRO-Q® by applying a small amount of the gel to an unbroken patch of skin and check within 24 hours. Minor redness is not a contraindication but where there is itching and 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 the use of HYDRO-Q® should be discontinued. HYDRO-Q® is formulated for the treatment of dyschromia and should not be used for the prevention of sunburn.
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 HYDRO-Q® 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 can affect reproductive capacity.

B. Nursing mothers

It is not known whether topical hydroquinone is absorbed or excreted in human milk. Caution is advised when 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 skin reddening and a mild burning sensation that does not preclude treatment

DOSAGE AND ADMINSTRATION

HYDRO-Q® should be applied to the affected areas twice daily, morning and before bedtime or as directed by a physician.

During and after the use of HYDRO-Q®, sun exposure should be limited and a sunscreen agent or protective clothing should be used to cover up the treated areas to prevent regimentation. If no lightening effect is noted after two months of treatment, use of HYDRO-Q® should be discontinued. There is no recommended dosage for children under the age of 12 years of age except under the advice and supervision of a physician.

HOW SUPPLIED

HYDRO-Q® (Hydroquinone 4%) Gel is supplied in a 30 g tube.

NDC: 30815-0040-1

Store at controlled room temperature, between 15° and 30°C (59°and 86°F).

REFERENCES

1. Denton C, Fitzpatrick TB, Lerner AB. Inhibition of melanin formation by chemical agents. J Invest Dermatology. 1952; 18: 119-135.
2. Fitzpatrick TB, Jimbow K, Obata M, Panthak M. Mechanism of depigmentation by hydroquinone. J Invest Dermatology. 1974; 62: 436-449.
3. 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.

Distributed by:
DermAvance Pharmaceuticals, Malvern, PA 19355
NDC 30815-0040-1

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PRINCIPAL DISPLAY PANEL - 30 g Tube Box

NDC 30815-0040-1

Rx Only

HYDRO-Q **4% GEL®**

(Hydroquinone 4%) Gel®

SKIN BLEACHING GEL

DermAvance®
Advanced Skin Care
www.DermAvance.com

30 g

HYDRO-Q
hydroquinone gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:30815-0040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydroquinone (UNII: XV74C1N1AE) (Hydroquinone - UNII:XV74C1N1AE)	Hydroquinone	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30815-0040-1	1 in 1 BOX	12/08/2008	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/08/2008	

Labeler - Dermavance Pharmaceuticals (046042475)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	MANUFACTURE(30815-0040)

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