

Glyquin•XM™

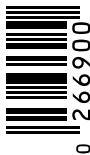
(Hydroquinone USP, 4%)
Skin Bleaching Moisturizing Cream
with Sunscreens (SPF 15)

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FOR EXTERNAL USE ONLY

I. DESCRIPTION

Each gram of Glyquin•XM™ contains 40 mg Hydroquinone USP, 80 mg Octocrylene USP, 40 mg Oxybenzone USP and 30 mg Avobenzone USP in a vanishing cream base of purified water USP, glycolic acid, poloxamer 407 NF, propylene glycol USP, glycerol monostearate, triethanolamine NF, polyoxyl 4 lauryl ether, lemon extract, propyl gallate NF, ascorbyl palmitate NF, vitamin E USP, methylparaben NF, edetate disodium USP, benzalkonium chloride and hyaluronic acid.



II. CLINICAL PHARMACOLOGY

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of tyrosine to 3,4-dihydroxyphenylalanine (dopa) (Denton, C. et al., 1952)¹ and suppression of other melanocyte metabolic processes (Jimbow, K. et al., 1974)².

III. INDICATIONS AND USAGE

Glyquin•XM™ is indicated for the gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentiginos and other unwanted areas of melanin hyperpigmentation.

IV. CONTRAINDICATIONS

Prior history of sensitivity or allergic reaction to this product or any of its ingredients. The safety of topical hydroquinone use during pregnancy or in children (12 years and under) has not been established.

V. WARNINGS

A. CAUTION: Hydroquinone is a skin bleaching 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 Glyquin•XM™ by applying a small amount to an unbroken patch of skin and check in 24 hours. Minor redness is not a contraindication, but where there is itching or 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 bleaching or lightening effect is noted after 2 months of treatment use, Glyquin•XM™ should be discontinued. Glyquin•XM™ is formulated for use as a skin bleaching agent 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. The sunscreens in Glyquin•XM™ provide the necessary sun protection during skin bleaching therapy. After clearing and during maintenance therapy, sun exposure should be avoided on bleached skin by application of a sunscreen agent or protective clothing to prevent repigmentation.

D. Keep this and all medication out of the reach of children. In case of accidental ingestion, call a physician or a poison control center 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 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 topical 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 adverse reactions have been reported. Occasional 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 from the use of topical hydroquinone in Glyquin•XM™. 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.

IX. DOSAGE AND ADMINISTRATION

Glyquin•XM™ should be applied to the affected area and rubbed in well 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.

X. HOW SUPPLIED

GLYQUIN•XM™ (Hydroquinone USP, 4%) is available as follows:

SIZE	NDC
1 ounce jar (28 grams)	0187-0421-46

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F).

REFERENCES

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



Manufactured by:
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3300 Hyland Avenue, Costa Mesa, CA 92626 U.S.A.

2669-00 EL
Orig. 6-02

Printed in U.S.A.

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