

MELAQUIN[®] CREAM 4% W/W WITH SUNBLOCK SPF 25

Ingredient(s):

Each gram contains:

Hydroquinone 40mg

Preservative:

Methyl paraben 1mg

Propyl paraben 1mg

Pharmacology (Summary of Pharmacodynamic and Pharmacokinetics):

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of tyrosine to 3, 4-dihydroxyphenylalanine and suppression of other melanocyte metabolic processes.

It may be several weeks before any effect is apparent but depigmentation may last for 2 - 6 months after discontinuation.

Indication(s):

Melaquin Cream 4% is used topically as a depigmenting agent for the skin in hyperpigmentation conditions such as chloasma (melasma), freckles, and lentigines (small macules that resemble freckles).

Dosage and Administration:

Melaquin Cream 4% should be applied twice daily to intact skin. Application should be discontinued if there is no improvement after 2 months of application.

To be applied onto the skin.

Contraindication(s):

Hypersensitivity or allergic reaction to this product or any of its ingredients.

Precaution(s) / Warning(s):

This product may cause transient erythema and a mild burning sensation. High concentrations or prolonged use may lead to hyperpigmentation especially on areas of skin exposed to sunlight. Avoid solar exposure. Stop use if skin irritation occurs.

This product should not be applied to abrade or sun burnt skin. It should not be used to bleach eyelashes or eye brows and contact with the eyes should be avoided as it may produce staining and corneal opacities.

Hydroquinone is a skin bleaching agent which may produce unwanted cosmetic effects if not used as directed. Test for skin sensitivity before using this product 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 eyes should be avoided. This product is formulated for use as a skin bleaching agent and should not be used for the prevention of sunburn. The safety of topical hydroquinone use during pregnancy, in nursing mothers or in children (12 years and under) has not been established.

This preparation contains Sodium metabisulfite that may cause serious allergic type reactions in certain susceptible patients. Do not use if known to be hypersensitive to bisulfite.

Interaction with Other Medicaments:

No related information has been reported.

Pregnancy and Lactation:

FDA 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 use 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 by pregnant women only when clearly indicated.

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.

Side Effect(s) / Adverse Reaction(s):

No systemic adverse reactions have been reported. Occasionally hypersensitivity has occurred. Hence, it is recommended to do skin testing before use. Ochronosis usually becomes apparent after about 6 months application of hydroquinone and, once established, is probably irreversible. Reversible brown discoloration of the nails has also been reported.

Symptoms and Treatment for Overdosage, and Antidote(s):

There have been no systemic reactions 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 transient skin reddening and a mild burning sensation which does not preclude treatment.

Shelf-Life:

3 years from the date of manufacture.

Storage Condition(s):

Keep in an airtight container. Store at temperature below 30°C. Protect from light and moisture.

Product Description & Packing(s):

A white to yellowish cream.

Aluminium tube of 10g, 15g, 20g, 10g x 50 tubes, 15g x 40 tubes, 15g x 72 tubes, 20g x 40 tubes and 20g x 72 tubes.



Manufacturer and Product Registration Holder:
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Product Info: 1 800 88 3679

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Date of revision: 27 Nov 2025