

TECHNICAL DATA SHEET

2564-TDS-ENG-2026

HIDROQUINONA USP (GMP EUR)		
DESCRIPTION DCI: HYDROQUINONE		DESCRIPTION DOE: HIDROQUINONA
CAS N°: 123-31-9	EC N°: 204-617-8	AEMPS CODE: 2024A
MOL. WEIGHT: 110,11	MOL. FORMULA: C6H6O2	ARTICLE CODE: 2564

<u>ATTRIBUTES</u>	<u>SHOULD BE</u>
Identification A	Complies
Identification B	Complies
Identification C	Complies
Melting range	172 - 174 °C
Water	=< 0.5 %
Residue on ignition	=< 0.5 %
Assay	99.0 - 100.5 %

COMPLIES WITH

USP 2025

STORAGE

Keep the container tightly closed, protected from light. Store it in a cool and dry place.

REMARKS

Hydroquinone is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses

HYDROQUINONE is a depigmenting agent that acts by interfering with the synthesis of melanin by inhibiting the tyrosinase-aminoglycine system. Due to this mechanism of action, the depigmentation is not immediate, but appears after 1 month. In addition, depigmentation is reversible, and sunscreen must be used during and after treatment. It is used topically in the treatment of alterations in skin pigmentation (hyperpigmentation), such as melasma, chloasma, freckles, senile pigmentations, lentigo, berloque dermatitis (photodermatitis due to perfumes), etc. use alone or associated with keratolytic substances (such as resorcinol, salicylic acid, glycolic acid, etc ...), retinoids, corticoids, or other depigmenting substances. It may take several weeks until some improvement is seen, but if no beneficial effects are seen in 2 months, treatment should be discontinued. In hydroalcoholic solutions it presents its maximum solubility once the hydroalcoholic mixture is made.

Dosage

Topical route, 2 - 5% for facial area and up to 6 - 8% on trunk and limbs, in the form of alcohol solutions, O / W creams and lotions, ointments, or gels, applied twice a day for 2 - 3 maximum months, on intact skin, and protecting it from exposure to solar radiation (a sunscreen is often included in the same preparation). Higher concentrations may be used in

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some severe cases (up to 10%). Allowed its use as a stabilizer in hair dyes. Prohibited its use as a cosmetic asset (depigmentation, etc ...).

Side effects

Repeated use or excessively high concentrations can cause local irritation, transient erythema, burning sensation, dryness, cracking of treated areas, and hyperpigmentation in areas with excessive exposure to sunlight, and therapy should be discontinued. Occasionally, hypersensitivity reactions occur, and a cutaneous tolerance test is recommended before use.

Precautions

It should not be used in areas close to mucous membranes, wounds, erythematous areas due to sun exposure or sunburn, eyes and surroundings, due to the risk of systemic toxicity, which may cause staining and opacity of the cornea on the eye. It should not be used to whiten lashes or eyebrows. Its use should be avoided in children, especially in children under 12 years of age.

Compounding examples*Depigmenting creams*HYDROQUINONE - **2 %**Retinoic acid - **0.05 %**Triamcinolone acetonide - **0.1 %**

Antioxidant c.s.

Cream Lanette c.s.p - **50 g**HYDROQUINONE - **3 %**Kojic acid - **2 %**

Antioxidant c.s.

Cream Lanette c.s.p. - **30 g**

Modus operandi: Spray the solids and the antioxidant in a mortar. Add a little propylene glycol to make a paste. Gradually add the cream Lanette in the mortar, working well with the pistil, until homogeneous. Pack quickly in opaque bottle.

*Hydrophilic ointment with HYDROQUINONE*HYDROQUINONE - **2 %**Retinoic acid - **0.05 %**Triamcinolone acetonide - **0.1 %**

Antioxidant c.s.

Hydrophilic ointment c.s.p. - **100 mL**

Modus operandi: Spray the solids and the antioxidant in a mortar. Add a little propylene glycol to make a paste. Add little by little the ointment in the mortar, working well with the pistil, until homogeneous. Pack quickly in opaque bottle.

*Solution for chloasma*HYDROQUINONE - **2 %**Retinoic acid - **0.05 %**Triamcinolone acetonide - **0.5 %**Propylene glycol - **100 mL**

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Antioxidant c.s.

Ethyl alcohol 96% c.s.p. - **200 mL**

Modus operandi: Spray the retinoic acid, the HYDROQUINONE, and the triamcinolone acetonide, mix with the propylene glycol, and add the 96% alcohol little by little. Add the antioxidant predisposed in the water.