

Eldoquin Forte® 4% Cream

(Hydroquinone USP, 4%) Skin Bleaching Cream

R_x Only

FOR EXTERNAL USE ONLY

I. DESCRIPTION

Each gram of Eldoquin Forte contains 40 mg of Hydroquinone USP in a vanishing cream base of purified water USP, stearic acid NF, propylene glycol USP, polyoxyl 40 stearate NF, polyoxyethylene (25) propylene glycol stearate, glycerol monostearate, light mineral oil NF, squalane NF, propylparaben NF and sodium metabisulfite NF.

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. Exposure to sunlight or ultraviolet light will cause repigmentation of bleached areas (Parrish, J.A. et al, 1978)³.

III. INDICATIONS AND USAGE

Eldoquin Forte is indicated for the gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentiginos and other unwanted areas of melanin hyperpigmentation. It is intended for night-time use only since it contains no sunblocking agents. For daytime usage, Solaquin Forte® or Eldopaque Forte® should be prescribed.

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 Eldoquin Forte 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, the medication should be discontinued.
- C. There are no sunblocking or sunscreens agents in Eldoquin Forte and since minimal sunlight exposure may reverse the bleaching effect of this preparation, it should be used only at night or on areas of the body covered by protective clothing. During daytime, sunblocking or broad spectrum sunscreen preparations or protective clothing should be used to prevent the bleached areas from repigmentation. For the daytime bleaching of unwanted pigmented areas, the use of Solaquin Forte or Eldopaque Forte should be considered.
- 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.
- E. WARNING: Contains sodium metabisulfite, a sulfite that may cause serious allergic type reactions (e.g. hives, itching, wheezing, anaphylaxis, serious asthma attacks) in certain susceptible persons.

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 children below the age of 12 years has 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 Eldoquin Forte. 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. DRUG DOSAGE AND ADMINISTRATION

Hydroquinone USP, 4% Cream should be applied to the affected area and rubbed in well twice daily or as directed by a physician to achieve maximum therapeutic potential. Eldoquin Forte® 4% Cream is intended to be used during night hours as the product contains no sun blocking agent. There is no recommended dosage for children under 12 years of age except under the advice and supervision of a physician.

X. HOW SUPPLIED:

ELDOQUIN FORTE is available as follows:

SIZE	NDC NUMBER
0.5 ounce tube (14.2 grams)	0187-0394-35
1.0 ounce tube (28.4 grams)	0187-0394-31

REFERENCES:

- Denton, C., A.B. Lerner and T.B. Fitzpatrick, "Inhibition of Melanin Formation by Chemical Agents", *Journal of Investigative Dermatology*, 18:119-135, 1952.
- Jimbow, K., H. Obata, M. Pathak, and T.B. Fitzpatrick, "Mechanism of Depigmentation by Hydroquinone", *Journal of Investigative Dermatology*, 62:436-449, 1974.
- Parrish, J.A., R.R. Anderson, F. Urbach, D. Pitts, *UVA, Biological Effects of Ultraviolet Radiation with Emphasis on Human Responses to Longwave Ultraviolet*. Plenum Press, New York and London, 1978, p. 151.

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

(THIS IS A MEDICAMENT)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

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