

**ELDOQUIN FORTE® 4% Cream (Hydroquinone USP, 4%)
(Skin Bleaching Cream)**

**ELDOPAQUE FORTE® 4% Cream (Hydroquinone USP, 4%)
(Skin Bleaching Cream with Sunblock)**

**SOLAQUIN FORTE® 4% Cream (Hydroquinone USP, 4%)
(Skin Bleaching Cream with Sunscreens, SPF 17)**

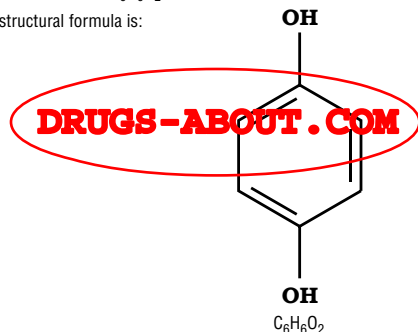
**SOLAQUIN FORTE® 4% Gel (Hydroquinone USP, 4%)
(Skin Bleaching Gel with Sunscreens)**

FOR EXTERNAL USE ONLY

DESCRIPTION

Hydroquinone is 1,4-benzenediol. Hydroquinone is structurally related to monobenzene. Hydroquinone occurs as fine, white needles. The drug is freely soluble in water and in alcohol and has a pK_a of 9.96. Chemically, hydroquinone is designated as p-dihydroxybenzene; the empirical formula is $C_6H_6O_2$; molecular weight 110.1.

The structural formula is:



Each gram of Eldoquin Forte 4% Cream contains 40 mg of Hydroquinone USP in a vanishing cream base of purified water USP, stearic acid NF, propylene glycol USP, polyoxyyl 40 stearate NF, polyoxyethylene (25) propylene glycol stearate, glycerol monostearate, light mineral oil NF, squalane NF, propylparaben NF and sodium metabisulfite NF.

Each gram of Eldopaque Forte 4% Cream contains 40 mg of Hydroquinone USP in a tinted sunblocking cream base of purified water USP, stearic acid NF, talc USP, polyoxyyl 40 stearate NF, polyoxyethylene (25) propylene glycol stearate, propylene glycol USP, glycerol monostearate, iron oxides, light mineral oil NF, squalane NF, edetate disodium USP, sodium metabisulfite NF and potassium sorbate NF.

Each gram of Solaquin Forte 4% Cream contains 40 mg of Hydroquinone USP, 80 mg Padimate O USP, 30 mg Dioxybenzone USP and 20 mg Oxybenzone USP in a vanishing cream base of purified water USP, glycerol monostearate and polyoxyethylene stearate, octyldodecyl stearoyl stearate, glyceryl dilaurate, quaternium-26, cetearyl alcohol and ceteareth-20, stearyl alcohol NF, propylene glycol USP, diethylaminoethyl stearate, polydimethylsiloxane, polysorbate 80 NF, lactic acid USP, ascorbic acid USP, hydroxyethyl cellulose, myristalkonium chloride and quaternium-14, edetate disodium USP and sodium metabisulfite NF.

Each gram of Solaquin Forte 4% Gel contains 40 mg of Hydroquinone USP, 50 mg of Padimate O USP and 30 mg Dioxybenzone USP, in a hydro-alcoholic base of alcohol USP, purified water USP, propylene glycol USP, entprol, carbomer 940, edetate disodium USP and sodium metabisulfite NF.

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 which may be prevented by the sunblocking agents contained in Eldopaque Forte 4% Cream and by the broad spectrum sunscreen agents contained in Solaquin Forte 4% Cream and Solaquin Forte 4% Gel (Parrish, J.A. et al., 1978).³

INDICATIONS AND USAGE

For the gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentiginos and other unwanted areas of melanin hyperpigmentation.

CONTRAINDICATIONS

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

WARNINGS

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 the package insert before prescribing or dispensing these medications.

Test for skin sensitivity before using 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, the medication should be discontinued. Eldoquin Forte 4% Cream, Eldopaque Forte 4% Cream, Solaquin Forte 4% Cream and Solaquin Forte 4% Gel are formulated for use as skin bleaching agents and should not be used for the prevention of sunburn.

Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight sustains melanocytic activity. The sunblock in Eldopaque Forte 4% Cream and the sunscreens in Solaquin Forte 4% Cream and Solaquin Forte 4% Gel provide the necessary sun protection during skin bleaching therapy. After cleaning and during maintenance therapy, sun exposure should be avoided on bleached skin by application of a sunscreen or sunblock agent or protective clothing to prevent repigmentation.

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.

Warning: Contains sodium metabisulfite, a sulfite that may cause serious allergic type reactions (e.g. hives, itching, wheezing, anaphylaxis, severe asthma attack) in certain susceptible persons.

PRECAUTIONS (SEE WARNINGS)

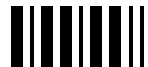
General. Treatment should be limited to relatively small areas of the body at one time since some patients experience a transient skin reddening and a mild burning sensation which does not preclude treatment.

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 by pregnant women only when clearly indicated.

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.

Pediatric usage. Safety and effectiveness in pediatric patients below the age of 12 years have not been established.





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.

DOSAGE AND ADMINISTRATION

Solaquin Forte 4% Cream and Solaquin Forte 4% Gel should be applied to the affected area and rubbed in well twice daily or as directed by a physician.

Eldopaque Forte 4% Cream should be applied to the affected area twice daily or as directed by a physician. Do not rub in.

Eldoquin Forte 4% Cream should be applied to the affected area and rubbed in well twice daily or as directed by a physician. During the day, an effective broad spectrum sunscreen should be used and unnecessary solar exposure avoided, or protective clothing should be worn to cover bleached skin in order to prevent repigmentation from occurring.

HOW SUPPLIED

ELDOQUIN FORTE 4% CREAM is available as follows:

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

ELDOPAQUE FORTE 4% CREAM is available as follows:

SIZE	NDC NUMBER
1.0 ounce tube (28.4 grams)	0187-0395-31
0.5 ounce tube (14.2 grams)	0187-0395-35

SOLAQUIN FORTE 4% CREAM is available as follows:

SIZE	NDC NUMBER
1.0 ounce tube (28.4 grams)	0187-0396-31
0.5 ounce tube (14.2 grams)	0187-0396-35

SOLAQUIN FORTE 4% GEL is available as follows:

SIZE	NDC NUMBER
1.0 ounce tube (28.4 grams)	0187-0523-31
0.5 ounce tube (14.2 grams)	0187-0523-35

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

Rx Only

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.
3. 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.



DRUGS-ABOUT.COM

ICN PHARMACEUTICALS, INC.
3300 Hyland Avenue
Costa Mesa, CA 92626, U.S.A.
(714) 545-0100