FOLIC ACID Tablets, USP

DESCRIPTION
Folic acid, 

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\text{H}_2\text{N} \quad \text{CH}_2 \quad \text{NH} \quad \text{CONH} \quad \text{CH}_2 \quad \text{NH} \quad \text{CONH} \quad \text{CH}_2 \quad \text{NH} \quad \text{CONH} \quad \text{CH}_2 \quad \text{CH}_2 \quad \text{N} \\
\text{N} \quad \text{CH}_2 \quad \text{N} \end{array}
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Each tablet, for oral administration, contains 1 mg folic acid.

Folic Acid tablets, USP 1 mg are yellow, functionally scored, round, standard convex debossed Tablets. Folic Acid tablets, USP 1 mg contain the following inactive ingredients: lactose monohydrate, magnesium stearate, sodium starch glycolate.

CLINICAL PHARMACOLOGY
Folic Acid acts on megaloblastic bone marrow to produce a normoblastic marrow.

IN INDICATIONS AND USAGE
Folic acid is usually indicated in the treatment of megaloblastic anemias of pregnancy. Folic acid is also indicated in certain other megaloblastic anemias in which vitamin B12 is deficient.

WARNING
CONTRAINDICATIONS
Pregnancy, infancy, or childhood.

PRECAUTIONS
Long-term studies in animals to evaluate carcinogenic potential and studies to evaluate the mutagenic potential or effect on fertility have not been conducted.

INDICATIONS AND USAGE
Folic acid is indicated in the treatment of megaloblastic anemias due to deficiencies of vitamin B12 or folate. Folic acid is also indicated in certain other megaloblastic anemias in which vitamin B12 is deficient.

CONTRAINDICATIONS
Pregnancy, infancy, or childhood.

ADVERSE REACTIONS
Anorexia, nausea, abdominal distention, flatulence, and a bitter or bad taste, have been reported in patients receiving 15 mg folic acid daily for 1 month. Other side effects reported in patients receiving 15 mg folic acid daily include abdominal pain, diarrhea, indigestion, itchy mouth, mouth ulceration, stomatitis, and impaired judgment.

OVERDOSAGE
In an uncontrolled study, orally administered folic acid was reported to increase the incidence of tumors in some epilastic patients receiving phenobarbital, primidone, or diphenylhydantoin.

DOSE AND ADMINISTRATION
Oral administration is preferred. Although most patients with malabsorption cannot absorb oral doses of folic acid, they are able to absorb oral folic acid orally. Parenteral administration is not indicated but may be necessary in some individuals (e.g., patients receiving parenteral or enteral alimentation). Doses greater than 1 mg should not be used unless anemia due to folate deficiency has been ruled out or is being adequately treated with a cobalamin.

OVERDOSAGE
Folic acid is relatively nontoxic in man. Rare instances of allergic responses to folic acid preparations have been reported and have included erythema, skin rash, itching, general malaise, and conjunctivitis. Folic acid is contraindicated in patients with a history of bromide sensitivity.

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