

Folic Acid

Foladin[®]
5 mg Tablet
HEMATINIC

FORMULATION:

Each tablet contains:
Folic Acid, USP 5 mg

DESCRIPTION:

Folic Acid 5 mg Tablet is a red, round, biconvex, film-coated tablet, plain on both sides.

PHARMACODYNAMICS:

Folic Acid (pteroylglutamic acid) in its reduced form of tetrahydrofolate serves as an important mediator in many reactions involving one-carbon transfers. Important reaction involves the conversion of homocysteine to methionine and of deoxyuridylylate to thymidylylate, an important step in DNA synthesis. It is also implicated in the conversion of some amino acids, and in the synthesis and utilization of formate. The deficiency of folic acid can lead to megaloblastic anemia which develops when dietary intake of folic acid is inadequate, such as megaloblastic changes in the bone marrow of several infants with severe diarrhea, malnutrition, and other infections; low birth weight and elevated homocysteine level in conditions such as in infants and children with chronic renal failure and heart disease; in reducing the prevalence and severity of neural tube defects in pre-conception and periconception.

PHARMACOKINETICS:

It is rapidly absorbed from the gastrointestinal tract, mainly from the duodenum and jejunum. Dietary folates have about half of the bioavailability of crystalline folic acid. Naturally occurring folate polyglutamates are largely deconjugated and reduced by dihydrofolate reductase in the intestines to form 5-methyltetrahydrofolate which appears in the portal circulation, where it is extensively bound to plasma proteins. Folic Acid administered therapeutically enters the portal circulation largely unchanged since it is a poor substrate for reduction by dihydrofolate reductase. It is converted to 5-methyltetrahydrofolate in the plasma and liver. Folate undergoes enterohepatic circulation. Folate metabolites are eliminated in the urine and folate excess of body requirements is excreted unchanged in the urine. Folate is distributed into breast milk. Folic Acid is removed by hemodialysis.

INDICATIONS:

Folic Acid is indicated in the treatment and prevention of folate deficiency state. It is also used in women of child-bearing potential and pregnant women to protect against neural tube defects in their offspring.

DOSAGE AND ADMINISTRATION:

For the treatment of folate-deficient megaloblastic anemia: 5 mg or 1 tablet daily for 4 months; up to 15 mg or 3 tablets daily in malabsorption states. Continued administration of 5 mg folic acid every 1 to 7 days may be necessary in chronic hemolytic state depending on the diet and rate of hemolysis.

For prevention of neural tube defects in the offspring of pregnant women and women with child-bearing potential: 5 mg or 1 tablet daily starting before pregnancy and continued through the first trimester or as prescribed by the physician.

CONTRAINDICATIONS:

Megaloblastic anemia secondary to vitamin B₁₂ deficiency. Folic Acid administration may produce hematologic remission while neurologic damage progresses. Folic Acid should not be given before a diagnosis has been fully established. Large and continuous doses of folic acid may lower the blood concentration of vitamin B₁₂.

PRECAUTIONS:

Folic Acid should never be given alone or in conjunction with inadequate amounts of vitamin B₁₂ for the treatment of undiagnosed megaloblastic anemia, since folic acid may produce a hematopoietic response in patients with megaloblastic anemia due to vitamin B₁₂ deficiency without preventing aggravation of neurological symptoms.

PREGNANCY AND LACTATION:

Folic Acid is excreted into breast milk. No adverse effects have been observed in breastfed infants whose mothers were receiving folic acid.

DRUG INTERACTIONS:

Folate deficiency states may be produced by a number of drugs including antiepileptics, oral contraceptives, antituberculosis drugs, alcohol, and folic acid antagonists such as aminopterin, methotrexate, pyrimethamine, trimethoprim, and sulfonamides.

ADVERSE EFFECTS:

Folic Acid is generally well tolerated. Gastrointestinal disturbances and hypersensitivity reactions have been reported rarely.

CAUTION:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING:

"For suspected adverse drug reaction, report to the FDA: www.fda.gov/ph. Seek medical attention immediately at the first sign of any adverse drug reaction."

STORAGE CONDITION:

Store at temperatures not exceeding 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

AVAILABILITY:

Aluminum strip foil x10's (Box of 100's)

REGISTRATION NUMBER:

DRP-1677-03

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21 January 2014

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Manufactured by:

HIZON LABORATORIES, INC.

Assumption Road, Sumulong Highway, Antipolo City

Distributed by:

MEDCHOICE WOMEN'S HEALTH (MCWH), INC.

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