FOLIC ACID

FOLIMAX

5 mg Tablet

HEMATINIC

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FORMULATION:
Each tablet contains:
Folic Acid..... 5 mg

DESCRIPTION:
Folic Acid (FOLIMAX) 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 deoxyuridylate to thymidylate, 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 preconception and periconception.

PHARMACOKINETICS:
It is rapidly absorbed from the gastrointestinal tract, mainly from the duodenum and jejunum. Dietary folates have about half the bioavailability of crystalline folic acid. Naturally occuring 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 in excess of body requirements is excreted unchanged in the urine. Folate is distributed into breast milk. Folic acid is removed through haemodialysis.

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 malabsoption states. Continued administration of 5 mg folic acid every 1 to 7 days may be necessary in chronic haemolytic state depending on the diet and rate of haemolysis.

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 B_{12} 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 continous doses of folic acid may lower the blood concentration of vitamin B_{12}.

PRECAUTIONS:
Folic Acid should never be given alone or in conjunction with inadequate amounts of Vitamin B_{12} for the treatment of undiagnosed megaloblastic anemia, since folic acid may produce a haematopoietic response in patients with megaloblastic anemia due to vitamin B_{12} 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, antituberculous 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**
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION:
Store at temperatures not exceeding 30ºC. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

AVAILABILITY:
Tablet - Box of 100's (Strip foil of 10's x 10)

REGISTRATION NO.:
DRP-1677-01

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Manufactured by:
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