Folic Acid

Maxifol 5000

5 mg Film-Coated Tablet

VITAMIN

FORMULATION:
Each film-coated tablet contains:
Folic acid ..... 5 mg

PHARMACOLOGICAL ACTIONS:
Folic acid is a member of the B vitamin group. It is involved in amino acid metabolism. Folic acid, in its reduced form, tetrahydrofolate, participates in many reactions involving one-carbon transfers. It is involved in the conversion of homocysteine to methionine and in the conversion of deoxyuridylate to thymidylate, an essential step required in the synthesis of DNA. As folic acid is necessary in the synthesis of DNA, it is essential in the formation of different body cells. Folic acid is necessary for the normal production and maturation of red blood cells. Deficiency of folic acid results in megaloblastic anemia.

Folic acid deficiency results in impaired processes of DNA synthesis, cellular replication and cell division. Cells with rapid turnover such as the red blood cells and the epithelial cells of the intestine may be readily affected. Deficiency of folic acid has been associated with birth defects (i.e., neural tube defects, congenital heart defects) certain cancers, blood disorders and higher risk of cardiovascular disorders as a result of homocysteinemia. Folic acid participates in the conversion of homocysteine into methionine. When folic acid is deficient, homocysteine levels increase, a condition known as homocysteinemia. Folic acid supplementation is considered protective against such disorders. Results of clinical studies suggest that high doses of folic acid help reduce risk of birth defects, cardiovascular diseases and cancer.

Folic acid deficiency may result from inadequate dietary intake, impaired intestinal absorption secondary to gastrointestinal diseases, alcoholism and intake of drugs that inhibit folate absorption (i.e., anticonvulsants, phenytoin, oral contraceptives, methotrexate). Dietary deficiency is common in the elderly, malnourished and individuals who do not eat vegetables and fruits. Despite adequate dietary intake of folic acid, relative deficiency may be encountered in certain conditions where there are increased requirements for active DNA synthesis (such as in pregnancy, and hematologic disorders). In these circumstances, folic acid supplementation becomes important.

PHARMACOKINETICS:
Folic acid is well absorbed in the gastrointestinal tract even in patients with malabsorption syndrome, so parenteral administration is rarely necessary. In the presence of malabsorption syndrome, folic acid from oral supplements will still be absorbed, whereas absorption of folic acid from food sources may be impaired.

Pteroylglutamic acid is the common pharmacological form of folic acid. Following oral administration, folic acid is rapidly absorbed from the gastrointestinal tract, mainly from the proximal part or the duodenum. The naturally occurring folate polyglutamate or folic acid polyglutamates from food sources are enzymatically hydrolyzed to monoglutamate forms in the gastrointestinal tract prior to absorption.

The peak folate activity in blood after oral administration is within 30 to 60 minutes. Following absorption, pteroylglutamic acid is rapidly reduced to tetrahydrofolic acid. Therapeutically administered folic acid enters the portal circulation largely unchanged since it is a poor substrate for reduction by dihydrofolate reductase. Folic acid is converted to the metabolically active form 5-methyltetrahydrofolate in the plasma & liver. The liver is the principal storage site of folate. Folate is also actively concentrated in the cerebrospinal fluid (CSF).

Folates are excreted in the urine and stool and are also destroyed by catabolism, so serum levels fall within a few days when intake is diminished. Because unaltered folic acid is readily and completely absorbed in the proximal jejunum. Folate in excess of body requirements is excreted unchanged in the urine. Folate is distributed into breast milk. Hemodialysis removes folic acid.

INDICATIONS:

- For the prophylaxis and treatment of megaloblastic anemia associated with folic acid deficiency (i.e., anemias of pregnancy, hemolytic anemias, exfoliative skin disease, pellagra, sprue, alcoholism, and that following gastrectomy, and in pernicious anemia).
- For the prevention of neural tube defects, including spina bifida and anencephaly.
- To correct decreased folate levels when taking the following: methotrexate, trimethoprim, sulfamethoxazole, phenytoin, oral contraceptive pills.
- For prophylaxis and treatment of diseases such as colorectal carcinoma, ulcerative colitis, dysplasia, sickle cell diseases, hereditary spherocytosis and homocysteinemia.

DOSAGE:

For prophylaxis and treatment of anemia associated with folic acid deficiency: one tablet daily.

For the prevention of neural tube defects in women at high risk: one to four tablets daily, taken at least one month before conception through the first trimester of pregnancy.

Or as prescribed by the physician.

DRUG INTERACTION:

Folic acid in large doses may interfere with the metabolism of phenobarbital, phenytoin, primidone and may partially reverse the antiepileptic effects of those drugs thereby increasing the frequency of seizures in susceptible patients.

Folic acid may interfere with the metabolism of certain medications, including antineoplastic agents such as methotrexate, oral contraceptive pills and anti-tuberculosis agents. Drugs that may interfere with the body's absorption of folic acid are analgesics / pain relievers such as NSAIDs, antibiotics (tetracycline), anticonvulsants (phenytoin, carbamazepine), antacids, epoetin, estrogens, oral contraceptives, methotrexate, pyrimethamine, triamterene, trimethoprim, sulfonamides and zinc supplements. Folic acid may interfere with the metabolism of these agents. Individuals who are taking these agents may need to take folic acid supplement. However folic acid should be taken at a different time of the day or should not be taken at the same time with these drugs because these drugs interfere with the absorption and effectiveness of folic acid.

CONTRAINDICATIONS:

Because it may mask the hematologic abnormalities while neurological damage progresses, folic acid should not be used in the therapy of patients with vitamin B12 deficiency of any cause, unless there is associated folate deficiency. The folic acid content of one tablet a day however, is unlikely to mask pernicious anemia, should this condition be present.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Folic acid is usually well tolerated in the dosage prescribed. It should not be given alone or in conjunction with inadequate amounts of vitamin B12 in the treatment of pernicious anemia. Proper hematological diagnosis is essential.

It may partially reverse the antiepileptic effects of phenobarbital, diphenylhydantoin, and primidone, and thereby increase seizure frequency.

CAUTION:

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

AVAILABILITY:

Foil strip x 10's (Box of 100's)

DR-XY34053

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Pnsv Asia

Manufactured for:
PNSV ASIA CORP.
4/F S.V. More Group Corporate Center
#16 Scout Tuazon cor. Roces Ave., Quezon City, Metro Manila, Philippines
by: Hizon Laboratories, Inc.
Assumption Road, Sumulong Highway
Antipolo City